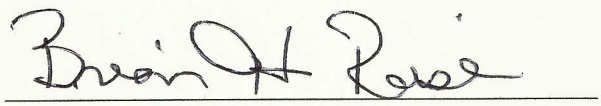
In re: National Prescription Opiate Litigation

MDL No. 2804

Cuyahoga County and Summit County, Ohio Cases

Expert Report of Brian H. Reise

May 31, 2019



Introduction

I, Brian H. Reise, was engaged by counsel at Williams & Connolly LLP to serve as an expert witness for Cardinal Health, Inc. (Cardinal) in cases brought by Cuyahoga County and Summit County, Ohio and consolidated in *In re: National Prescription Opiate Litigation*, MDL No. 2804. My opinions are stated below. I reserve the right to supplement or amend this report after review of additional materials or information as they become available to me.

I am being compensated for my time spent working on this matter based on my hours actually expended at the rate of $350 per hour. I have not offered expert testimony at a deposition or trial at any point in the past four years.

I. Summary of Opinions[1]

It is my opinion, based on my experience, training, and the facts and information discussed herein, that at all relevant times:

1) Cardinal maintained effective controls against diversion;

2) Cardinal maintained and implemented appropriate systems to monitor and report Suspicious Orders consistent with the requirements of 21 CFR 1301.74(b), articulated standards, policies, and regulations of the Drug Enforcement Administration (DEA), and prevailing industry standards;

3) Cardinal acted reasonably and, at times, in reliance upon DEA approval in the design and operation of its Suspicious Order Monitoring (SOM) systems; and

4) Criticisms of those systems made by Plaintiffs' witnesses Rafalski and Whitelaw are unfounded, contradicted by evidence, and inconsistent with applicable standards, policies, and regulations promulgated by the DEA.

II. Summary of Qualifications

A. Experience at DEA

I have almost 32 years of federal service with the Department of Justice. For over 26 years, I was employed with the Drug Enforcement Administration as a Diversion Investigator, and was in a supervisory capacity for more than 17 of those years. Before the DEA service, I was employed for over five years with the Federal Bureau of Prisons as a Senior Correctional Officer.

During my DEA service, I conducted complex investigations and established training objectives for the Diversion Control Program and assisted in formulating DEA policy matters. I carried out

[1] A more complete statement of my opinions is contained in the rest of this Report. My opinions are not limited by this summary.

the integrity of the program and was instrumental in detecting and preventing the diversion of controlled substances (domestic and foreign).

October 1987 to February 1997 – Drug Enforcement Administration, Diversion Investigator, Greensboro Resident Office, Greensboro, North Carolina

After graduating from the DEA Training Academy in 1987 as a Diversion Investigator, I conducted over 100 investigations. Many of these investigations resulted in arrests and thousands of dollars in fines and forfeitures from doctors, pharmacies and others that diverted pharmaceutical controlled substances. Many other cases resulted in administrative actions such as restricted or surrendered DEA registrations.

February 1997 to September 1998 – Drug Enforcement Administration, Diversion Group Supervisor, Greensboro Resident Office, Greensboro, North Carolina

As the Group Supervisor, I supervised the DEA Diversion Group consisting of four Diversion Investigators, and one Group Assistant. While maintaining my current case load, I also planned, coordinated and provided oversight on the group's investigations. I monitored the investigators' progress and activities and assumed prime responsibility for the integrity of the group, and managed overall aspects of the investigations. I ensured that all investigations were conducted within the scope of federal drug laws and were in accordance with the agency's rules, policies and regulations. I also provided oversight on scheduled (cyclic) investigations conducted on DEA registrants that manufacture, distribute, import, and export controlled substances.

September 1998 to September 2000 – Drug Enforcement Administration, International Drug Unit, Office of Diversion Control, DEA Headquarters, Arlington, Virginia

As a Staff Coordinator, I coordinated and monitored diversion program activities as they related to international matters. This involved working closely with the DEA field offices and other governmental entities (domestic and foreign) to implement and enforce the Controlled Substances Act (CSA), the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971), the Convention Against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances (1988), and appropriate regulations contained within the Code of Federal Regulations as they related to import and export matters. I also assisted in formulating DEA policy relating to these topics.

September 2000 to December 2001 – Drug Enforcement Administration, Course Developer/Instructor, Academic Training Unit, Office of Training, DEA Training Academy, Quantico, Virginia

In 2000, I was temporarily reassigned to the DEA Training Academy and assumed the duties of Course Developer/Instructor for a Diversion Basic Training Class. Within the Academic Training Unit, as Course Developer/ Instructor, I was responsible for developing, implementing and evaluating the training of diversion personnel. While in this position, I updated the Basic Diversion Investigator Training Program, which had not been extensively updated since the late 1980s. I was also responsible for proposing and seeking approval for the development of the

Diversion Training Unit. After the unit was approved, I drafted a mission statement for the unit and the position descriptions for the Unit Chief, Course Developer/ Instructor and support personnel positions.

December 2001 to June 2004 – Drug Enforcement Administration, Unit Chief, Diversion Training Unit, Office of Training, DEA Training Academy, Quantico, Virginia

In 2001, I assumed the duties of Unit Chief of the Diversion Training Unit. In that role, I was responsible for directing entry-level, in-service, and specialized training of DEA Diversion Investigators. The position required extensive knowledge of the job requirements of Diversion Investigators and required resourcefulness and ingenuity in order to originate a training program of sufficient scope and intensity to accomplish program goals. While there, I established training objectives and curricula design of each specific program of training within the unit. This included making detailed plans covering subject areas and methods of instruction which would provide trainees with sufficient expertise to detect and prevent the diversion of illegally manufactured controlled substances and chemicals into the illicit market. I was responsible for providing expert instruction in the areas of diversion investigations to include pharmacology, chemical and drug identification, pharmaceutical drug manufacturing and distribution practices, retail pharmacy operations, auditing procedures, practitioner operations, narcotic treatment programs, chemical manufacturing and distribution, interview and interrogation methods, administrative, civil and criminal law procedures, report writing and DEA's organization, policies, and procedures, as well as many other disciplines which are pertinent to drug diversion.

According to the information provided in his report, Plaintiff's witness James Rafalski arrived for training as a Diversion Investigator in the fall of 2004, shortly after I completed my duties as Unit Chief of the Diversion Training Unit. Assuming that is correct, he would have received his training based on the curriculum and materials that I oversaw and helped establish.

June 2004 to January 2014 – Drug Enforcement Administration, Diversion Group Supervisor, Greensboro Resident Office, Greensboro, North Carolina

In June 2004, I completed my assignment as Unit Chief of the Diversion Training Unit, and was reassigned to the Greensboro field office as the Group Supervisor, for the second time. In that role I supervised the DEA Diversion Group now consisting of 10 Diversion Investigators, one Intelligence Analyst, two support staff and one student intern. I planned, coordinated, and oversaw scheduled and complaint investigations. I monitored the investigators' progress and activities and assumed prime responsibility for the integrity of the group, and managed overall aspects of the investigations. I also ensured that all investigations were conducted within the scope of federal drug laws and in accordance with the agency's rules, policies and regulations. I was also responsible for giving lectures and presentations at training seminars for federal, state and local officials and the DEA registrant community representatives. I monitored and provided oversight on regulatory investigations conducted on DEA registrants that manufacture, distribute, import, and export controlled substances. I also monitored and had oversight on investigations that encompassed the trafficking of legitimate pharmaceutical drugs and listed chemicals to illegal channels.

In conducting complaint investigations, I would depend on a variety of informational sources. Most information in the form of leads would come from "cold calls" into the office where citizens or a cooperating individual provided information of alleged wrongdoing. Additional leads could be referrals from other federal, state and local law enforcement or regulatory agencies. In the earlier years of my career, I would also use the ARCOS quarterly reports as an information source. The majority of complaint investigations initiated by myself were based on information received from citizen complaints, cooperating individuals and referrals from other agencies.

* * *

Throughout my tenure as a DEA Diversion Investigator, I was assigned, on an annual basis, scheduled (cyclic) investigations to be conducted on manufactures, distributors, importers, exporters, narcotic treatment programs, and researchers located in North Carolina. In conducting these scheduled investigations, I applied my knowledge, training, and various procedures detailed in the DEA's Diversion Investigators Manual. As a general matter, these investigations included conducting an accountability audit on a select number of controlled substances, inspecting all security containers, (i.e., vault, safe, cage, etc.), ensuring the firm's compliance with CFR regulations, and reviewing required records (such as DEA Form 222's, controlled substance invoices, theft or loss reports, drug destruction forms and ARCOS reports). In addition, I would review the registrant's policies and procedures as they pertained to the receipt, distribution, and security of controlled substances as well as their standard operating procedures.

As the Group Supervisor of the Greensboro North Carolina Diversion Group, I was responsible for reviewing the group's scheduled (cyclic) investigations reports to ensure protocols, as it pertains to scheduled investigations, were followed as detailed in the Diversion Investigators Manual. Furthermore, as Group Supervisor I would review the accountability audit results, any findings identified during the investigation and ensured that the report was complete and accurate. Beginning in the late 2000s (approximately 2008-2010 time period), a required step in the conduct of a cyclic investigation was to obtain documentation verifying that the registrant (e.g., a wholesale distributor) continued to have a Suspicious Order Monitoring Program designed to identify for further review and/or reporting orders of unusual size, frequency, or pattern. As Group Supervisor, I annually reviewed dozens of cyclic investigation reports to ensure that they had verified the registrants' compliance with this, and all other required, actions.

B. Private-Sector Experience

On January 3, 2014, I retired from DEA and formed my own consulting business, Controlled Pharmaceutical Consultants, Inc.

As a Pharmaceutical Compliance Consultant, I have continued applying my knowledge and training accrued as a Diversion Investigator, Supervisor, and Chief of the Training Unit to assist registrants with their compliance with the CSA and federal regulations. Among other things, I have provided the following services to manufacturers, wholesale distributors and other registrants:

- Assist clients in ensuring compliance with DEA regulations and reporting requirements as requested.

- At the request of clients, conducts audits for controlled substance compliance in manufacturer, distributor, and pharmacy environments to assist in preventing diversion.

- Audits may include more in-depth reviews to assist organizations in the implementation and monitoring of the overall performance of their controlled substance compliance and security programs.

- If requested, to conduct reviews of an organization's controlled substance compliance standard operating procedures, physical security requirements (i.e., locks, keys, camera surveillance, and DEA storage areas (vaults, cages, and safes)), suspicious order monitoring procedures and downstream due diligence efforts, as well as reviews of dispensing activities in pharmacy environments as requested.

- If requested, assist organizations in interfacing with the DEA as required on issues relating to reporting requirements and other miscellaneous requests.

- If requested, assist clients in coordinating internal investigative and review efforts in assuring follow-up of actions requested by regulatory authorities.

- Assist clients, if called upon, in submitting reporting to regulatory bodies to help the client in resolving questions and concerns.

- Provide training on all topics relevant to the CSA and CFR as it pertains to pharmaceutical controlled substances.

C. Education

In May 1991, I received a Bachelor of Science degree, *cum laude,* in Fisheries and Wildlife from North Carolina State University in Raleigh, North Carolina.

III. Regulatory Overview

A. Federal Statutes and Regulations

The CSA, at 21 USC 823, details factors to be considered by the Attorney General through the DEA in determining whether to allow registration of a distributor for the purpose of distributing controlled substances:

(b) Distributors of controlled substances in Schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in Schedule I or II unless he determines that the issuance of such registration is

inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

The DEA has defined the "maintenance of effective controls" that it considers in its regulations at 21 CFR 1301.71(a): "In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." The distribution chain consists of DEA registrants transferring controlled substances from one registrant to another utilizing the required documentation.

The corresponding CFR regulations, 21 CFR 1301.72 through 1301.74 detail the physical, electronic, and regulatory security requirements for all non-practitioner registrants.[2] Most of these provisions contain highly-detailed instructions on registrants' obligations, for example, specifying the dimensions and building materials necessary for the construction of a secure vault, 21 CFR 1301.72(a). Included in these is Section 1301.74(b), which requires registrants to report suspicious orders placed by their customers:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

In contrast with the other regulations cited above that have detailed implementing instructions, the term "suspicious order" has only this one general definition to guide registrants and Diversion Investigators.

Additionally, 21 CFR Part 1304 requires distributors to maintain inventories and certain other records. The inventories and records covered "must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration."[3]

The CSA regulations do not establish a requirement to conduct due diligence on customers or orders. With respect to suspicious order monitoring, the CSA regulations state only that a distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." DEA witnesses in this litigation have acknowledged that the CSA regulations, including 1301.74(b), do not mention due diligence.[4] The DEA has not issued any formal guidelines that describe how due diligence should be conducted.[5]

The CSA regulations also do not establish a requirement that due diligence files be maintained, as Tom Prevoznik, testifying as DEA's representative, testified.[6] As explained above, the CSA regulations set forth requirements that certain records be maintained for two years. Records relating to customer due diligence are not included in either category, and the DEA has never

[2] 21 CFR 1301.75 and 1301.76 apply only to practitioner registrants.

[3] 21 CFR 1304.04(a).

[4] Kyle Wright Deposition Tr. 496:8-14; Tom Prevoznik Deposition Tr. 1213:18-1221:7.

[5] Tom Prevoznik Deposition Tr. 1213:18-1221:7.

[6] *Id.*

issued guidance stating that registrants must maintain such records for any period of time or in any particular manner.[7]

Similarly, there is also no requirement to maintain records relating to reports of suspicious orders. Like records relating to due diligence, suspicious order reports are not included in the list of records that are required to be maintained for two years. Tom Prevoznik, testifying as DEA's representative, similarly acknowledged in this litigation that there is not "any sort of requirement, either by the DEA or by the registrant, to hold on to an actual suspicious order being reported to the DEA" and that the DEA has never issued guidance indicating how long a record of a suspicious order that's been reported must be maintained.[8]

B. DEA Enforcement

Pursuant to guidance contained in the CSA, CFR, training, the Diversion Investigators Manual (versions of which have been made public through FOIA requests), and DEA policies and guidelines, a pre-registration investigation is conducted on all non-practitioner applicants. "The pre-registration investigation is to ensure that the applicant is familiar with the responsibilities to prevent the diversion of controlled substances and list I chemicals."[9] For distributor applicants, this involves conducting the investigation onsite.[10] This investigation involves, among other things, verifying information on the application, obtaining background information on the applicant's corporate structure, their knowledge and experience in handling controlled substances, the name, address, and identifying information of corporate officers and upper management. Construction details of the applicant's buildings are reviewed for perimeter security. Physical and electronic security are identified and tested to confirm it is operational and the signal to the alarm company is received in a timely manner. Security containers, such as vaults, safes and/or cages are inspected to ensure construction and regulatory requirements are met. Information is obtained on all personnel having access to controlled substances and background checks are conducted. Diversion Investigators discuss with the applicant's management, their record keeping requirements for controlled substances. This includes DEA Form 222 Schedule I or II Order Forms; controlled substance invoices; DEA Form-106, Theft or Loss; DEA-41, Registrant Record of Controlled Substance Destroyed; ARCOS reporting; and quota inventory (manufacturers). During the course of the pre-registration investigation, "the applicant is to be made aware of … all provisions of the CSA and C.F.R."[11] A DEA witness in this matter, Tom Prevoznik, testified that if the DEA determines during the pre-registration

[7] *Id.*; Kyle Wright Deposition Tr. 497:6-14.

[8] Tom Prevoznik Deposition Tr. 1213:18-1221:7.

[9] 2012 Diversion Investigators Manual, CAH_MDL2804_01483146, at 272.

[10] *Id.*

[11] *Id.* at 277.

process that the applicant's suspicious order monitoring system is inadequate, the Diversion Investigators conducting the investigation would inform the applicant of that fact.[12]

Once a non-practitioner applicant is approved and becomes a registrant, the next onsite visit from DEA typically will be in the form of a scheduled investigation. The purpose of the scheduled investigation is to ensure the information, policies, and procedures detailed in the pre-registration investigation remain compliant with the CSA, CFR, and DEA guidance. Prior to the on-site inspection, the investigator checks the appropriate databases and conducts a file check on the registrant.[13] The file check includes reviewing the registrant's previous scheduled investigation or if new, the registrant's preregistration report. The investigator also checks the registrant's company file for any past discrepancies. Also prior to the inspection the ARCOS Unit at DEA Headquarters is contacted to ensure that the registrant is properly filing its ARCOS reports and that there are no significant outstanding error reports.[14] The on-site inspection includes a review of background information, which includes ascertainment of the registrant's reporting procedures for thefts and loss, and "the firm's system for identifying suspicious/excessive orders."[15] The on-site inspection also includes the conducting of an inventory for controlled substances being audited, review of receiving and sales records, and review of general recordkeeping requirements.[16] As described in the Diversion Investigators Manual: "A review of the firm's monitoring system for detecting unusual sales should be performed in order to determine whether it complies with regulations."[17] The physical and electronic security is inspected and tested to make sure they are still operational. Other security measures are reviewed for changes and to ensure they are in compliance with the law and regulations.[18]

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[12] Tom Prevoznik Deposition Tr. 131:15-21.

[13] 2012 Diversion Investigators Manual, CAH_MDL2804_01483146, at 299.

[14] *Id.*

[15] *Id.* at 300. In my experience, at least during part of my time as Diversion Group Supervisor, Diversion Investigators would obtain a copy of the registrant's Standard Operating Procedure for its suspicious order monitoring program and make it an attachment to the schedule investigation report. Investigators were also instructed to obtain a copy of the system and make it an attachment to their scheduled investigation report.

[16] *Id.* at 300-302. In conducting the review of the primary controlled substance records, the investigators have the option not to review all of the records within the audit timeframe. For distributors, a minimum of one year of controlled substance records are to be reviewed and used to conduct the accountability audit. Depending on the timing of the inspection the investigators may have to go back and use two years' worth of records. In lieu of using the primary records, the investigators are allowed to use a secondary record, a computer-generated document, that when attested to its accuracy by the registrant, is used to perform the audit. However, the investigators are required to select a random number of primary records and cross verify them with the secondary records. If there are any discrepancies between the two records the investigators are required to use the primary records.

[17] *Id.* at 302.

[18] *Id.* at 303-304.

At the conclusion of the on-site investigation and at the direction of the Group Supervisor, the lead investigator on the scheduled investigation discusses with the firm management all discrepancies and/or violations identified during the scheduled investigation.[19] Based on this discussion, the firm's management should be advised of possible actions DEA can take against the firm for said discrepancies or violations. When possible, the investigator is to make recommendations on what the company can do to get back into compliance.[20]

At the conclusion of the scheduled investigation, the investigator is to conduct a sales/purchase transaction verification.[21] This gives the investigator the opportunity to review and verify order/sales of interest.

In my experience, following the approval of a non-practitioner registrant's application, it was routine for DEA to return within one year to conduct a first scheduled investigation. Non-practitioner registrants continue to receive scheduled inspections at regular intervals. Since 2009, most non-practitioner registrants (including distributors) receive a scheduled investigation every three years.[22] These scheduled investigations "serve as a deterrent to diversion through the continuous evaluation of registrants' recordkeeping procedures, security, and overall adherence to the CSA."[23] Also, if a scheduled investigation on a non-practitioner resulted in some form of administrative, civil, or criminal action, in my experience, it was routine for that registrant to be scheduled for a follow-up inspection within two years.

For a wholesale distributor registrant like Cardinal, each of its distribution centers is a separate registrant. Therefore, each distribution center receives an individual preregistration investigation before opening, an individual scheduled investigation within one year of the approval of its registration, and an individual scheduled investigation every three years thereafter.

At the conclusion of a scheduled investigation, if the circumstances warrant it, DEA may pursue criminal, civil, or administrative action against a distributor and/or its staff. Noncompliance with the CFR is documented as a discrepancy and not a violation. Only noncompliance with the CSA can constitute a violation. Discrepancies are generally dealt with through administrative actions. Administrative actions taken against a registrant can come in different forms. They include a

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[19] *Id.* at 304 ("It is important for the Investigators to discuss all of the violations noted (including copies of violative documents) and to denote the appropriate section of the CFRs and/or the CSA which was violated.").

[20] *Id.*

[21] *Id.*

[22] Controlled Substances and List I Chemical Registration and Reregistration Fees, 76 Fed. Reg. 39,318, 39,324 (July 6, 2011). Before 2009, non-practitioner registrants were scheduled for investigation every five years. *Id.* The change in frequency was designed "to help the registrant population better comply with the CSA." *Id.*

[23] *Id.* at 39,322.

verbal reprimand, a Letter of Admonition, a Memorandum of Agreement, Administrative Hearing, Request of an Order to Show Cause and an Immediate Suspension. Depending on the severity of the discrepancies, an action could start with a verbal reprimand and progress to a stronger action if the same discrepancies continue over time. However, if the discrepancies warrant it, a more stringent action can be taken such as a Request of an Order to Show Cause or an Immediate Suspension. Another administrative action available to investigators is the voluntary surrender of part or all of a registrant's DEA schedules in lieu of initiating a Public Interest Revocation.

C. DEA Training and Guidance

I attended an eight week Basic Diversion Investigator (DI) training from October to December 1987. Among other books and publications, we were issued a new copy of the Diversion Investigator Manual. I received legal instruction, instruction on drug identification, computer database training, instruction on how to conduct an accountability audit, lectures on ARCOS, DAWN, and quotas as well as other topics directly or indirectly related to the position of Diversion Investigator. I also received lectures on security. As part of our training, for which we were tested on, the instructors went over the CSA and CFR throughout the eight weeks.

After completing my training, I reported to the DEA Greensboro Resident Office. There I became aware of reports submitted by registrants, generally known as "Excessive Purchase Reports." My supervisor at the time would routinely go through these reports and on occasion, assign specific pages out of the report detailing the transactions involving a particular registrant in North Carolina. In reviewing these documents, I became aware that certain registrants were generating a report that contained purchases by their customers that exceeded a preset formula.

In general, and without disclosing the details of specific investigations, these Excessive Purchase Reports were used in our investigations of individual registrants. Among other uses, they gave us insight into ongoing orders from pharmacies that were the subjects of investigations. Also, our office would occasionally receive reports from other DEA offices detailing excess purchases made by a registrant in North Carolina. As a general practice, the supervisor would assign these reports to the group, but again, a single report would not on its own cause an investigation to be opened. However, when additional excessive purchase reports were received or other relevant information on the registrant in question, the reports would become sources of information used in the investigation.

Diversion Investigator Training 2001-2004

In September of 2000, I was given the opportunity to teach at the DEA Academy, in Quantico, VA, and to take over the responsibilities of the Basic Diversion Investigator Training. In 2001, with the assistance of 5-6 Senior Diversion Investigators from across the country, I updated the Basic Diversion Investigator Training Program, which had not been extensively updated since the late 1980s. This included all new audit problems and extensive report writing throughout the training. Consistent with DEA's position that it is up to registrants to design their own Suspicious Order Monitoring (SOM) systems based upon knowledge of their customers, the standard curriculum (CSA and CFR) we taught to trainees did not instruct that there was any

single correct design for an SOM system. In other words, the standard training for Diversion Investigators did not include a basis for judgments Rafalski purports to make in his report.

D. Regulation of Manufacturers, Pharmacies, Pharmacists and Prescribers

21 CFR 1301.71 states, "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."

A manufacturer must apply for quotas, procurement or production, from DEA before they can purchase and manufacture a Schedule I or II controlled substance. Manufacturers are required to be registered with the FDA, DEA, and the appropriate state agencies. Besides transaction records for controlled substances, a manufacturer is required to maintain records for all levels of production. They are also required to enter specific controlled substance transaction into ARCOS.

In contrast a distributor registered with DEA is not responsible for maintaining records of quotas or production records. Furthermore, a distributor need not be registered with FDA.

Prescriptions for controlled substances must meet the requirements detailed in 21 CFR 1306. More specifically, a controlled substance prescription must be issued by a practitioner acting in the normal course of their professional practice. For example, a dentist should not be writing prescriptions for a cough syrup with codeine. Additionally, the prescription must be issued for a legitimate medical purpose.

It is the pharmacist's responsibility to evaluate the controlled substance prescription for compliance with the above criteria. 21 CFR 1306.04(a) states in part, "An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."

The board of pharmacy in each respective state is responsible for credentialing the pharmacy, pharmacist in charge, and pharmacy technicians and conducting inspections on said pharmacies. Some of these boards may be government agencies, quasi-government agencies, and others are privately governed by their peers. It is also my understanding that some of these boards are responsible for registering manufacturers and distributors.

Prescribers must meet their own requirements when issuing a prescription for a controlled substance. The prescriber must be acting in the course of his or her professional practice and there must be a legitimate medical purpose for issuing the prescription. Licensing and investigations of prescribers are conducted by the professional boards, i.e. medical board, dental board, etc., in the respective states. Some of these boards may be government agencies, quasi-government agencies, and others are governed by their peers.

IV. Opinions

In my opinion, and for the reasons stated herein, Cardinal adopted reasonable and appropriate systems for detecting and reporting suspicious orders in conformance with 21 CFR 1301.74(b) and changing DEA expectations. In addition, those systems were properly implemented for the registered distribution center from which Cardinal serviced customers in Cuyahoga and Summit Counties.

A. Opinion: Cardinal Reasonably Complied with the Suspicious Order Reporting Regulation During the Period it Submitted "Ingredient Limit Reports," Consistent with DEA Expectations, Industry Standards, and Prevailing Practice

Based on my experience, training, and review of documents produced in the litigation, it is my opinion that DEA approved, as consistent with 21 CFR 1301.74(b), the use of a system that identified "excessive" orders after they had been shipped. As stated above, those reports were commonly provided by registrants at the time I began my career as a Diversion Investigator. In my opinion, it would be evident to any Diversion Investigator from the face of those reports that they identified shipments of controlled substances, which had been identified for inclusion in the report after they had been shipped. These reports were received at DEA field offices, including the one at which I was assigned, and were used in various ways in support of investigations.

Documents produced in the litigation provide further support for that opinion. In the early 1980s, the National Wholesale Druggist Association (NWDA) began working with the DEA to design a suspicious order monitoring system.[24] That system had two components. The first component was a process for monthly, after-the-fact reporting of excessive purchases. Each distribution center would "review all purchase transactions involving DEA schedule classifications II through V on a monthly basis."[25] Excessive purchases were identified based on an algorithm that calculated "ingredient limits" based on average sales of certain categories of customers multiplied by a factor to be provided by DEA.[26] Once identified through this algorithm, the transaction would be included in a monthly report that would be sent to the respective DEA field office.[27] The second component was a process for identifying and reporting "single suspicious orders" that are identified prior to shipment.[28]

In 1984, the NWDA submitted the proposed system to DEA for approval. Thomas Gitchel, who at that time was the Acting Chief of the Diversion Operations Section within the Office of

[24] "NWDA Suspicious Order Monitoring System" Memo and April 27, 1984 and May 16, 1984 Letters from Thomas Gitchel, Acting Chief, Diversion Operations Section, CAH_MDL2804_01465723.

[25] *Id.* at 725.

[26] *Id.*at 726-727.

[27] *Id.* at 727-730.

[28] *Id.* at 730.

Diversion Control, wrote a letter in which he described NWDA's proposed system as providing "an excellent framework for distributor registrants to '… design and operate a system to disclose to the registrant suspicious orders of controlled substances.' (21 CFR 1301.74(b).)"[29] In a follow-up letter, Gitchel stated that "[t]his system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b)."[30]

In addition to NWDA's proposed suspicious order monitoring system, DEA approved a number of similarly designed systems in the 1980s and 1990s. In 1988, Ronald Buzzeo, the Deputy Director of the Office of Diversion Control, wrote that Walgreen's proposed system for detecting and reporting excessive orders was "based on an average monthly sales figure multiplied by an arbitrarily selected deviation factor, which is one of the key elements in devising an effective reporting system."[31] Between 1996 and 1998, DEA oversaw the gradual implementation of Bergen Brunswig's newly designed suspicious order monitoring system that was based on entirely on post-shipment reporting.[32] In 1998, Patricia Good, the Chief of the Liaison and Policy Section, approved Bergen Brunswig's request to implement its newly developed system on a nationwide basis.[33]

The fact that the DEA had approved suspicious order monitoring systems that were based in part on after-the-fact reporting of excessive purchases was known by the Office of Diversion Control.[34] For example, in 1998, the Suspicious Order Task Force on the Comprehensive Methamphetamine Control Act of 1996 issued a report to the U.S. Attorney General.[35] One of the purposes of this report was to develop criteria that wholesale distributors of List I chemicals could use to identify suspicious orders. The Task Force recommended that List I chemical distributors "use the DEA-approved Suspicious Order Monitoring System in use by wholesale drug distributors for controlled substances."[36] The Task Force's recommendation for reporting excessive or suspicious orders of List I chemicals, as summarized in Exhibit II of its report, outlined a methodology that was "basically what is done for Schedules II through V controlled substances."[37] It consisted of five steps, the final of which stated: "At the end of each month a

[29] *Id.* at 732.

[30] *Id.* at 734.

[31] Letter from Ronald Buzzeo, Deputy Director, Office of Diversion Control, to Walgreen Company (Dec. 27, 1988), US-DEA-00025683.

[32] Letters Exchanged Between Bergen Brunswig Corporation and DEA, September 30, 1996 through July 23, 1998, ABDCMDL00315783.

[33] *Id.*

[34] Kyle Wright Deposition Tr. 72:4-75:9, 487:7-492:4.

[35] CAH_MDL_PRIORPROD_HOUSE_0002207.

[36] *Id.* at 230.

[37] *Id.*

report will be transmitted to DEA … of all purchases of List I chemicals and or/C-II-V controlled substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period."[38] The Report also noted that "using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious."[39]

Based on my review of Cardinal documents and deposition transcripts, Cardinal's initial suspicious order monitoring system was consistent with the DEA-approved NWDA system. From the 1990s through at least 2007, Cardinal had two written policies and procedures that explained the process by which Cardinal met its obligations pursuant to 21 CFR 1301.74(b).[40] The first, called the DEA Compliance Manual, was created in 1995 and, at least since the version from 2000 that I have reviewed, established a two-step system for reporting suspicious orders.[41] It also included a section titled, "Test and Training Manual for Distribution Center Employees Handling Controlled Substances," and exhibits which were sample copies of the forms and reports discussed in the Compliance Manual.[42] There were several versions of the DEA Compliance Manual, until 2006, when the policies in the Manual were restated in the Standard Operating Procedures: Corporate Quality and Regulatory Compliance.[43]

Cardinal's DEA Compliance Manual states that, "[w]holesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders" and informing the "DEA field office in that area of all suspicious orders."[44] It explains that "[s]uspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency" and that "DEA has no specific form for" reporting suspicious orders.[45] The Compliance Manual states that "[w]holesalers should establish written criteria of what constitutes a suspicious order" and that "DEA leaves it to the wholesaler to make this determination."[46] The Compliance Manual states that DEA permits the wholesaler to use

[38] *Id.* at 247.

[39] *Id.*

[40] Steve Reardon Deposition Tr. 503:8-506:5; Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895; Standard Operating Procedures, Corporate Quality and Regulatory Compliance, CAH_MDL_PRIORPROD_DEA07_01188323.

[41] CAH_MDL_PRIORPROD_DEA07_01383895, at 939-940; *see also* Steve Reardon Deposition Tr. 506:12-506:19.

[42] CAH_MDL_PRIORPROD_DEA07_01383895, at 013, 040-041, 080.

[43] Steve Reardon Deposition Tr. 506:3-506:5; CAH_MDL_PRIORPROD_DEA07_01188323.

[44] CAH_MDL_PRIORPROD_DEA07_01383895, at 939.

[45] *Id.*

[46] *Id.*

"[e]ither a computerized or manual system . . . depending upon the wholesaler's preference and capability."[47]

The Compliance Manual then explains Cardinal's "two-step process" for complying with 21 CFR 1301.74(b).[48] As step one, Cardinal submitted monthly ingredient limit reports to the local DEA field office.[49] Ingredient Limit Reports were Cardinal's "excessive purchase reports." They were "based on a computer program which monitor[ed] customer controlled substance purchases for a month and compare[d] these purchases to predetermined averages or limits."[50] If any "customer's purchase quantities exceed[ed] the established parameters, the customer's activity [was] printed on the report."[51]

Cardinal has produced a sampling of Ingredient Limit Reports from 2005 to 2008.[52] From these reports and the SOPs, certain observations can be made. First, customers were classified each month into the following groups: (a) hospitals/managed care, (b) retail customers, and (c) other.[53] Then, for each of these categories, Cardinal calculated the total grams of each schedule II-V controlled substance purchased in the last twelve months and divided that number by the number of customer months (twelve).[54] This yielded the monthly average grams purchased by customers in each classification. These monthly averages were then multiplied by one factor for ARCOS-reportable substances and a higher factor for non-ARCOS-reportable substances to generate the maximum amounts of controlled substances that customers could order before their orders would be included in the Ingredient Limit Report.

The factors used by Cardinal varied over time. For example, based on a sample of a report from 1995 that was included as Exhibit M to Cardinal's DEA Compliance Manual, Cardinal used a

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[47] *Id.*

[48] *Id.* at 940.

[49] *Id.*; Steve Reardon Deposition Tr. 506:21-23.

[50] CAH_MDL_PRIORPROD_DEA07_01383895, at 940.

[51] *Id.*

[52] August 2005 Wheeling Distribution Center Ingredient Limit Report (Sept. 4, 2005), CAH_MDL_PRIORPROD_DEA07_01465435-R; October 2006 Phoenix Distribution Center Ingredient Limit Report (Nov. 12, 2006), CAH_MDL_PRIORPROD_DEA07_02769065-R; April 2008 Hudson Distribution Center Ingredient Limit Report (May 9, 2008), CAH_MDL2804_00690982.

[53] This approach followed the approach described in the DEA's 1998 Suspicious Orders Task Force report. Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 165.

[54] The approach followed the approach in the DEA-approved NWDA Suspicious Order Monitoring System, "NWDA Suspicious Order Monitoring System" Memo and April 27, 1984 and May 16, 1984 Letters from Thomas Gitchel, Acting Chief, Diversion Operations Section, CAH_MDL2804_01465723, at 726.

factor of 2,[55] but some of its reports from 2005 indicate a factor of 4 for ARCOS-reportable substances.[56] The factor used for each report was stated on the top left corner of each report, which ensured DEA was aware of the factor being used at all times.[57] The Ingredient Limit Reports also showed the customer's name, the customer's address, and the customer's DEA registration number.[58] Then, for each family of a controlled substance, the Report showed all of the customer's orders for that family, and for each order, the dates of the order, the order number, the item number, the NDC number, the item description, the narcotic code, the quantity ordered, the amount of active ingredient in grams, and the total amount in grams of the active ingredient.[59] The Report also stated the total grams the customer purchased for each family of a controlled substance by adding up the total grams purchased for each order for that family.[60] Immediately below that number, the Report listed the ingredient limit.[61]

Testimony supports that Cardinal provided this report to the DEA each month.[62] Additionally, when the DEA conducted cyclic inspections of distribution centers, the DEA reviewed the reports as part of its inspection.[63] The Cardinal representative responsible for oversight of this system testified that DEA never communicated to Cardinal concerns related to the Ingredient Limit Reports.[64]

Rafalski quotes a portion of the 1996 DEA Diversion Investigators Manual discussing suspicious orders, and states, "If Cardinal Health designed its system in accordance with the DEA Diversion Investigators Manual (1996), a copy of which it had in its possession since at least 2003, it would have identified a serious problem in Cuyahoga County and Summit County."[65] Rafalski's statement is confused. Rafalski does not provide a citation for his claim that Cardinal had the 1996 Manual in its possession since 2003. An email from Cardinal's Bob Giacalone states that

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[55] Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 157.

[56] August 2005 Wheeling Distribution Center Ingredient Limit Report (Sept. 4, 2005), CAH_MDL_PRIORPROD_DEA07_01465435-R, at 517-R.

[57] August 2005 Wheeling Distribution Center Ingredient Limit Report (Sept. 4, 2005), CAH_MDL_PRIORPROD_DEA07_01465435-R; *see also* Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 157.

[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] *Id.*

[62] Steve Reardon Deposition Tr. 508:9-17.

[63] *Id.*

[64] *Id.* at 509:2-8.

[65] Rafalski Report 55.

he received it "via a FOIA request in 2007."[66] To the extent Rafalski is suggesting that Cardinal should have revised its policies based on the language he quotes from the 1996 Manual, I disagree. The Manual is not a public document, so its contents would not have been known to Cardinal before it was obtained via FOIA in 2007. As I discuss elsewhere in my report, Cardinal undertook a revision of its SOM procedures that year in response to different statements by DEA, and it would not have been reasonable for Cardinal to have instead relied on a Manual from 1996. In addition, the last three sentences of the statement quoted by Rafalski is not one that in my experience provides relevant guidance. That is confirmed by the fact that, when DEA issued a new version of the Manual in 2012, the language quoted by Rafalski had been dropped.[67] Finally, to the extent Rafalski is suggesting Cardinal should have adopted a system that would treat any order above "the average" for all orders as potentially "suspicious," I disagree for the reasons stated in Part IV.G of my report.

As described above, the generation and provision of Ingredient Limit Reports was step one of Cardinal's two-step system for complying with its obligations pursuant to 21 CFR 1301.74(b). For step two, evidence shows that employees at distribution centers who were involved in filling orders "police[d]" customer orders on a daily basis.[68] These employees were the "cage and vault personnel," where "cage and vault" is a reference to the physical security measures employed by Cardinal to secure controlled substances.[69] These employees were required to identify any orders that "appear[ed] excessive" based on the employees' knowledge of and experience with that customer or other customers' buying.[70] If the cage and vault personnel identified any orders that appeared excessive, they were required to pull the order and hold it.[71] The distribution center would then contact the local DEA office.[72] Guidance or specific instructions from the DEA was noted on a "Regulatory Agency Contact Form."[73] Distribution centers maintained copies of this form.[74] There was no uniform requirement from DEA to maintain such records

[66] Email from Bob Giacalone (Jan. 18, 2012), CAH_MDL2804_02203346 (attaching undated letter from DEA granting FOIA request, CAH_MDL2804_02203353).

[67] 2012 Diversion Investigators Manual, CAH_MDL2804_01483146.

[68] Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 940; Steve Reardon Deposition Tr. 512:3-9.

[69] CAH_MDL_PRIORPROD_DEA07_01383895, at 940, 942.

[70] Steve Reardon Deposition Tr. 512:3-9.

[71] *Id.*

[72] *Id.*

[73] CAH_MDL_PRIORPROD_DEA07_01383895, at 940.

[74] *Id.* Examples of these forms include CAH_MDL2804_02395109, at 110 ("Called to inform [DEA Investigator] Chuck [Carpenter] of the high quantities of Hydrocodone that was being ordered by Woody's Pharmacy") ; CAH_MDL2804_01345344, at 345 ("DEA gave permission for the following Walgreens to have excessive purchase of oxycodone/APAP …"); CAH_MDL2804_02395115, at 119 ("Notify DEA of possible excessive purchase").

and my understanding is that these documents from the files of the Wheeling, West Virginia distribution center from early time periods are no longer available.

To help cage and vault personnel monitor customer orders on a daily basis, Cardinal created a "Dosage Limit Chart," which was posted in each distribution center's cage and vault.[75] The Chart listed products that were "commonly audited by DEA" during the agency's inspections of Cardinal's distribution centers as well as those that "ha[d] a high potential for diversion."[76] To create this Chart, Cardinal used dosage limits "set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items."[77] The Chart provided information only; cage and vault personnel were required to still use their knowledge and experience of a customer's order history as well as other customers' order history to determine whether to pull and hold an order and report it as suspicious to the DEA.[78] Cardinal's Eric Brantley testified that only "the best" of Cardinal's employees were "selected to work in the cage and vault area."[79]

Cardinal's Reardon testified that the dosage limit charts were not a bright line over which orders were to be reported or held.[80] In my opinion, the use of such a document as a general guide, rather than as a hard limit, is consistent with the definition of "suspicious" orders in 21 CFR 1301.74(b).

Testimony from Reardon shows that there were additional, appropriate checks on controlled substance orders. Each schedule II order was on a DEA Form 222.[81] Once an order was received, a Cardinal employee reviewed the form to ensure it was in compliance with the regulation, and, signed and dated it if that was the case.[82] The employee then entered the order into Cardinal's system.[83] A picker at the distribution center would then look at the form and pull the appropriate quantity, and then record on Cardinal's copy of the DEA Form 222, the amount

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[75] Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 940, 160-161.

[76] *Id.*

[77] *Id.* It is unclear from the face of the document at what point in time that average was calculated, though the document contains a revision date placing it in 2000. In general, the "average" orders of various pharmaceuticals could be expected to change over time.

[78] Steve Reardon Deposition Tr. 512:16-513:4.

[79] Eric Brantley Deposition Tr. 534:12-19.

[80] Steve Reardon Deposition Tr. 512:10-513:4; 495:6-10.

[81] *Id.* 513:14-514:13.

[82] *Id.*

[83] *Id.*

shipped and the date of shipment.[84] Before shipping, a separate quality control clerk then conducted a final check.[85] Cardinal kept one copy of DEA Form 222, the DEA got a second copy, and the customer kept a third copy.[86] By virtue of receiving the DEA Form 222's, the DEA had a record of every order for controlled substances filled by Cardinal.

For all of the above reasons, it is my opinion that the system used by Cardinal through 2007, including the submission of Ingredient Limit Reports, was reasonable and consistent with the parameters recommended and approved by DEA for satisfaction of 21 CFR 1301.74(b), as well as prevailing industry standards of the time.

In my opinion, DEA's acceptance of excessive purchase reports like Ingredient Limit Reports should be understood in light of the various tools at its disposal. In my experience, DEA investigations rarely start with reported suspicious orders. When DEA Diversion Investigators are evaluating whether a pharmacy's controlled substance orders indicate it may be engaged in diversion, investigators are more likely to start with the pharmacy's own records or ARCOS data, which offer a more complete picture of the totality of the pharmacy's ordering behavior. While excessive purchase reports had a role in investigations, and could be the source of helpful leads, they were just one of several tools available to support ongoing investigations.

B. Opinion: Cardinal Reasonably Understood the Guidance Provided by DEA at its August 2005 Internet Distributor Initiative Meeting to Address Only Internet Pharmacies

In the preceding section, I discuss Cardinal's system for detecting and reporting suspicious orders through the use of a DEA-accepted method of submitting excessive purchase reports and excessive order reports to DEA. In this section, I address why Cardinal moved on from that system and designed the next iteration of its suspicious order monitoring system, discussed in Part IV.C below.

Evidence in the record shows that on August 22, 2005, DEA personnel and representatives from Cardinal attended a meeting at DEA Headquarters.[87] Cardinal's representatives included Steve Reardon, the company's Vice President for Quality & Regulatory Affairs who oversaw regulatory compliance, including compliance with anti-diversion regulations.[88] The topic of the meeting, including a PowerPoint presentation titled "Internet Pharmacy Data," was regarding

[84] *Id.*

[85] Cardinal Health DEA Compliance Manual, CAH_MDL_PRIORPROD_DEA07_01383895, at 964.

[86] Steve Reardon Deposition Tr. 513:14-514:13.

[87] Memo from Michael Mapes to Joe Rannazzisi re Meeting with Cardinal Health, Inc. Concerning Internet Pharmacies (Aug. 23, 2005), US-DEA-00000352.

[88] Steve Reardon Deposition Tr. 500:5-500:16; "Now and Then" Document (May 14, 2008), CAH_MDL2804_02156859.

issues involving internet pharmacies.[89] DEA met with other wholesalers and gave them the same presentation.[90]

At these presentations, the DEA asked wholesalers to monitor internet pharmacies, which were "becoming a growing problem."[91] The DEA gave the attendees "a take-away binder, and identified certain items that an Internet pharmacy may purchase."[92] The DEA also identified factors to take into consideration in identifying internet pharmacies, including "Frequency of Orders," "Size of Orders," "Range of Products Purchased," "Payment Method," "Pharmacy Location," "% Controlled vs. % Non-Controlled," and "Customer pick up at distributor."[93] The DEA also told attendees that internet pharmacies can seek accreditation through the National Association of Boards of Pharmacy.[94]

Reardon testified that following this meeting, he started developing a process and program for Cardinal to monitor internet pharmacy activity.[95] He worked with Eric Brantley, a Cardinal employee in the role of Director, Quality and Regulatory Affairs.[96] Brantley's role required him to review Ingredient Limit Reports and "identify pharmacies that would need further investigation."[97] He would conduct due diligence investigations, which included site visits, of suspected internet pharmacies and make a recommendation whether to terminate and report pharmacies to the DEA as suspected internet pharmacies.[98] Cardinal conducted due diligence on suspected internet pharmacy customers identified by the DEA, and both terminated customers and reported them to the DEA based on the findings of that due diligence.[99]

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[89] US-DEA-00000352; Materials Documenting Cardinal Health's Response to Internet Pharmacy Briefing, CAH_MDL2804_02102254.

[90] Steve Reardon Deposition Tr. 515:13-21.

[91] Steve Reardon Deposition Tr. 515:13-24.

[92] *Id.* at 515:22-24.

[93] US-DEA-00000352, at 354.

[94] Steve Reardon Deposition Tr. 516:8-11.

[95] *Id.* at 517:17-21.

[96] *Id.* at 518:1-6; CAH_MDL2804_02156859, at 859-860; Eric Brantley Deposition Tr. 520:9-14.

[97] Eric Brantley Deposition Tr. 135:9-16, 536:16-537:3.

[98] Steve Reardon Deposition Tr. 518:1-6; Eric Brantley Deposition Tr. 535:17-536:1, 537:16-537:3.

[99] Email from Eric Brantley (Jan. 9, 2006) CAH_MDL2804_01305528 (flagging possible internet pharmacy identified while reviewing Ingredient Limit Reports); Email from Eric Brantley (Jan. 27, 2006) CAH_MDL2804_02102795 ("Please do not ship product to this customer. The DEA has alerted us of suspected internet activity by this customer. Prior to shipping any product to this customer I need to visit the customer's facility and conduct an investigation."); Documentation of Due Diligence Conducted by Eric Brantley on Several Pharmacies, CAH_MDL2804_00283431; Email from Eric Brantley Recommending Discontinuation of Shipments to Customer (Sept. 29, 2006),

Brantley also developed an "Internet Pharmacy Policy" for Cardinal in 2005, which laid out its practices regarding customer approval, oversight, reporting, and investigations.[100] Brantley trained senior management and sales staff on internet pharmacies, and ensured all sales staff received this training by July 2006.[101] He created a presentation titled "Internet Pharmacy: Approval and Oversight," to use in the sales staff training.[102]

Additionally, distribution center employees were also instructed to monitor pharmacy customers' orders.[103] If pharmacies ordered over 3000 dosage units of phentermine or 5000 dosage units of hydrocodone per month, those pharmacies were to be flagged for review.[104] In a contemporaneous email, Brantley stated that these threshold numbers came from the DEA.[105]

When Cardinal had questions on how to implement DEA's internet pharmacy policy, it asked DEA.[106] For example, DEA had explained in its August 2005 presentation that "[p]rescriptions can only be issued by a doctor acting in the usual course of professional practice."[107] On December 22, 2005, Reardon emailed Michael Mapes at DEA to ask about "different scenarios regarding the doctor patient relationship."[108] Mapes discussed the issue with DEA's legal

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CAH_MDL_PRIORPROD_DEA07_02067586; *see also* Letter from Eric Brantley to Jan Hamilton, Diversion Investigator, Miami Field Division, DEA, and Kyle Wright (Apr. 27, 2007), CAH_MDL2804_02102142, at 145 (identifying internet pharmacies shut down by Cardinal Health); Eric Brantley Deposition Tr. 523:6-9.

[100] Internet Pharmacies: Customer Approval and Oversight Policy (Dec. 19, 2005), CAH_MDL2804_02102254, at 259-263.

[101] Letter from Eric Brantley to Jan Hamilton, Diversion Investigator, Miami Field Division, DEA, and Kyle Wright (Apr. 27, 2007), CAH_MDL2804_02102142, at 144.

[102] "Internet Pharmacy: Approval and Oversight" Presentation (Apr. 2006), CAH_MDL_PRIORPROD_DEA07_01175050.

[103] Internet Pharmacies: Customer Approval and Oversight Policy (Dec. 19, 2005), CAH_MDL2804_02102254, at 258.

[104] Email from Steve Reardon re Internet Pharmacies (Aug. 30, 2005), CAH_MDL_PRIORPROD_DEA07_02088028.

[105] Email from Eric Brantley (Jan. 9, 2006), CAH_MDL_PRIORPROD_DEA07_02075690.

[106] Emails exchanged between Michael Mapes and Steve Reardon (Dec. 22, 2005 – Jan. 3, 2006), CAH_MDL2804_02102241.

[107] Memo from Michael Mapes to Joe Rannazzisi re Meeting with Cardinal Health, Inc. Concerning Internet Pharmacies (Aug. 23, 2005), US-DEA-00000352.

[108] Emails exchanged between Michael Mapes and Steve Reardon (Dec. 22, 2005 – Jan. 3, 2006), CAH_MDL2804_02102241.

counsel and responded that a legitimate doctor-patient relationship required face to face contact and an examination of the patient by the prescribing doctor.[109]

During this time period, when Cardinal terminated customers, it informed the DEA.[110] The DEA would regularly compile a list of customers terminated by one or more distributors and share that list with distributors.[111] Cardinal circulated this list internally, and also terminated customers based on their inclusion in this list.[112] A DEA witness, June Howard, testified that DEA subsequently stopped circulating this list to distributors out of concern that pharmacies would not be able to acquire medications for which they and their patients had legitimate medical needs, and that it could result in litigation.[113]

In mid-March 2007, DEA Diversion Investigators from field offices in Florida inspected Cardinal's distribution center in Lakeland, Florida.[114] On the second day of the visit, the investigators spoke to Brantley, who "answered specific questions pertaining to [Cardinal's] internet pharmacy procedures (investigations, etc.)."[115] Another QRA employee noted that "it was clear the visit pertained to internet pharmacy activity."[116]

In late April 2007, Cardinal learned that another distributor, AmerisourceBergen, had received an immediate suspension order at one of its distribution centers for activity related to "rogue internet pharmacies."[117] Reardon and Brantley contacted Kyle Wright, a DEA Diversion

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[109] *Id.*

[110] Email from Steve Reardon to Deborah.Y.Butcher@usdoj.gov (Jan. 9, 2006), CAH_MDL2804_02102246; Email from Steve Reardon to Deborah.Y.Butcher@usdoj.gov (Jan. 27, 2006). CAH_MDL2804_02102247.

[111] Email from Kyle Wright (July 20, 2007), CAH_MDL_PRIORPROD_DEA07_02075115 (providing list of customers that distributors had recently notified DEA they were discontinuing or restricting business with).

[112] *Id.*; Eric Brantley Deposition Tr. 555:21-557:2.

[113] June Howard Deposition Tr. 47:2-48:8.

[114] Email from Elaine Trautman, Senior Consultant, Quality & Regulatory Affairs, Cardinal Health, to Steve Reardon and others (Mar. 19, 2007), CAH_MDL2804_01319576.

[115] *Id.*

[116] *Id.*

[117] Email Forwarding Press Release: "AmerisourceBergen Receives DEA Order to Temporarily Halt Distribution of Controlled Substances from Its Orlando, Florida Facility" (Apr. 25, 2007), CAH_MDL2804_01320109; Press Release, "DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances" (Apr. 24, 2007), CAH_MDL_PRIORPROD_DEA07_02078411; Steve Reardon Notes from Conversation with Kyle Wright (Apr. 26, 2007), CAH_MDL2804_02102228; Steve Reardon Deposition Tr. 521:20-524:13.

Investigator, two days later on April 26.[118] Among other items, Reardon's handwritten notes from that call state:[119]

- "Think doing right thing"
- "right direction"
- "Eric establish great relationship"
- "ABC decision was not made by his office. very little input. made higher."

Reardon summarized this call for other Cardinal executives the next day, stating that DEA's Kyle Wright "thinks we are doing the right things and heading in the right direction."[120]

In my opinion, it would be reasonable for Cardinal to have understood such comments as unofficial or implicit approval of its efforts at the time directed towards identifying internet pharmacies. That is because, prior to this time (including in the examples reviewed above) DEA historically worked with industry to help them satisfy their obligations under 21 CFR 1301.74(b), including by commenting on particular systems. Although that practice was changing (as discussed further below) to one of cooperating less with registrants, Cardinal reasonably would have understood Wright's comments in light of the historical practice up until that point.

On the same day as Reardon's conversation with Wright, Brantley sent a letter to a Diversion Investigator at the DEA's Miami Field Office, which set out the steps Cardinal had taken to address rogue internet pharmacies, including trainings for all sales staff and specific actions taken against suspected internet pharmacies.[121]

In September 2006 and February 2007, DEA issued letters, virtually identical, to Cardinal and other distributors.[122] The letters describe, in more detail, the laws and regulations on the responsibilities of a registrant to detect and prevent the diversion of controlled substances. Designing and operating a suspicious order program and exercising due care in confirming the legitimacy of all orders prior to filling was also discussed. Although the letters reiterated the requirement to report the suspicious orders to DEA, the letters did not indicate that Cardinal (distributors) needed to submit their reports any differently than what they were already doing.

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[118] Steve Reardon Notes from Conversation with Kyle Wright (Apr. 26, 2007), CAH_MDL2804_02102228; Steve Reardon Deposition Tr. 521:20-524:13.

[119] Steve Reardon Notes from Conversation with Kyle Wright (Apr. 26, 2007), CAH_MDL2804_02102228.

[120] Email from Steve Reardon re Conversation with Kyle Wright (Apr. 27, 2007), CAH_MDL2804_02102142.

[121] *Id.*

[122] CAH_MDL_PRIORPROD_DEA07__00837645 at 646; CAH_MDL_PRIORPROD_DEA12_00002471 at 472.

Indeed, the letters state that "DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."[123]

In my opinion, and in view of the events discussed above, Cardinal reasonably understood it to be a continued expression of DEA's approval of Cardinal's existing SOM processes. Steve Reardon commented that "based on meeting with the DEA, the reason for this letter is diversion of controlled substances by internet pharmacies where there is not a valid doctor/patient relationship."[124] Reardon went on to explain that Cardinal was already in compliance with DEA's internet pharmacy initiative based on prior interactions with DEA. Specifically, Reardon stated, "Cardinal has an anti-diversion program, managed by Eric Brantley, which includes the monitoring of internet pharmacy activity. Eric has a close working relations with DEA HQ and they are very supportive of the program we have in place."[125] There are other parts of the letters that are not specific to internet pharmacies. However, in view of the letters' acknowledgement that the "overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion," and recognizing that the system Cardinal used was consistent with prevailing standards of the time, it would not have been reasonable to read these letters as requesting significant changes to the design of such programs at that time.

C. Opinion: In 2007 and 2008, Cardinal Designed and Implemented an Anti-Diversion System Consistent with DEA Expectations, Industry Standards, and Prevailing Practice

In my opinion, the first true indication that broader changes were coming on how DEA would ask registrants to report their suspicious orders was in September 2007. On September 7, 2007, representatives from DEA and HDMA (Healthcare Distribution Management Association) met to discuss suspicious orders. Pursuant to a summary of the meeting sent from HDMA to Cardinal, three important points were documented:

1. "DEA's policy was to expect more than just reporting 'suspicious orders'. If there was a suspicious order, the distributor should either stop the delivery or should evaluate the customer further before delivering it."

2. "DEA was clear that the 'system' mentioned above did not need to be the same for each wholesaler distributor."

3. "DEA also does not want to receive suspicious order reports that merely reflect volumes that went over a threshold; they wanted reports that are "true' suspicious

[123] *Id.*

[124] CAH_MDL_PRIORPROD_DEA07_00848351.

[125] CAH_MDL_PRIORPROD_DEA07_00848351; *see also* CAH_MDL_PRIORPROD_DEA07_02093469; Cardinal Health's Revised and Supplemental Response to 30(b)(6) Notice 1, Topic (a).

> orders. Similarly, they do not want to receive what they called 'excessive purchase' reports which had been used in the past."[126]

One example of an SOM system that introduced to distributors during this time period was AmerisourceBergen's. In September 2007, the DEA asked AmerisourceBergen (ABDC) to present its SOM system at an industry conference in Houston, Texas. DEA did not mandate that all distributors adopt ABDC's SOM system. At that conference, Chris Zimmerman of ABDC presented to the attendees on ABDC's new suspicious order monitoring program.[127] ABDC's "Diversion Control Program" had four components: "Know Your Customer" Due Diligence; Order Monitoring Program; Investigations; and Education & Training.[128] Chain pharmacies were exempted from ABDC's due diligence investigations for new customers.[129] Steve Reardon's handwritten notes on this slide indicate that either DEA said that or he inferred that DEA was "ok" with ABDC's decision to exempt chain pharmacies.[130] His notes also indicated that sales made the site visits. The ABDC presentation acknowledged that "[h]istorically Controlled Substance / Listed Chemical order monitoring has been based on a ship and report process," but described ABDC new order monitoring program as being "based on identify, capture, investigate, and report suspicious orders; all prior to shipment."[131] The presentation states that ABDC would now base its thresholds on class of trade and customer size, and hold orders once a threshold was hit. Steve Reardon testified that, after the presentation, DEA told the assembled industry members that ABDC's program "was going to be the new standard for the industry with respect to how suspicious orders were monitored, reported, and handled."[132]

On September 14, 2007, Steve Reardon emailed Cardinal employees regarding the HDA meeting with DEA and the ABDC presentation.[133] In the email, Reardon stated that "DEA is setting a new standard with which we must comply."[134] Reardon testified that this new standard "was a change in the way that -- moving away from the ingredient limit report and there was -- the biggest thing that came out to me here was they were clear-cut that -- do not ship."[135] Reardon immediately

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[126] CAH_MDL_PRIORPROD_DEA07_01198345, at 346-347.

[127] *Id.* at 345, 348-358.

[128] *Id.* at 350.

[129] *Id.* at 351.

[130] Steve Reardon's Notes on AmerisourceBergen Presentation (Sept. 11, 2007), CAH_MDL2804_02101840; Steve Reardon Deposition Tr. 528:11-529:4 (stating that this document contains his handwritten notes).

[131] CAH_MDL_PRIORPROD_DEA07_01198345, at 352.

[132] Steve Reardon Deposition Tr. 528:19-24; *see also* Steve Reardon Deposition Tr. 529:15-23.

[133] CAH_MDL_PRIORPROD_DEA07_01198345.

[134] *Id.*

[135] Steve Reardon Deposition Tr. 529:15- 530:6.

began a "proactive" plan to "implement a program that we develop, that will satisfy DEA expectations and that is not dictated to us by the Agency pursuant to regulatory action."[136]

DEA provided similar information in a letter to manufacturers and distributors on December 27, 2007.[137] Unlike the previous two letters, this letter suggested that DEA expects distributors not to ship suspicious orders:

> Registrants must conduct an independent analysis of suspicious orders **prior to completing a sale** to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.[138]

The letter also stated that registrants who "routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."[139] Further, the letter withdrew prior implicit and explicit approvals of registrants' systems, stating, "[p]ast communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a particular system.

In my opinion, this letter conveyed new and different DEA expectations, which were also first communicated to DEA Diversion Investigators at around the same time. As a general practice, DEA field offices would receive copies of correspondence to registrants to use as a reference when addressing inquiries from registrants.

In 2007 and 2008, Cardinal designed and implemented an SOM system consistent with the changing DEA expectations, while continuing to remain in compliance with the requirements of 21 CFR 1301.74(b). In a declaration submitted in connection with the 2012 DEA enforcement action, Cardinal's Michael Moné stated that he changed Cardinal's SOM program to comport with the new guidance from DEA.[140] "I have held the position of Vice President for Supply Chain Integrity for Cardinal Health since December 2007. In this role, I modified Cardinal Health's anti-diversion program that existed in December 2007 to comport with the DEA's letters to distributors dated December 27, 2007, informing them that, in addition to detecting and reporting suspicious orders in accordance with 21 C.F.R. § 1301.74(b), a distributor must not fill 'suspicious orders' unless the distributor determines that the controlled substances are not likely to be diverted into illegitimate channels. Under my supervision and guidance, Cardinal Health

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[136] *Id.*; CAH_MDL_PRIORPROD_DEA07_01198345.

[137] CAH_MDL_PRIORPROD_DEA12_00010980.

[138] *Id.* (emphasis added).

[139] *Id.*

[140] *See* Moné Declaration ¶ 3 (Feb. 6, 2012), CAH_MDL_PRIORPROD_DEA12_00014224.

has continuously improved its anti-diversion program and adapted it to the ever-changing nature of diversion."[141] Based on my review of Cardinal's system during this time period, I agree with Moné's assessment.

Consistent with the system that AmerisourceBergen presented at DEA's request, Cardinal's revised SOM system set monthly thresholds based on customer type and size, adjusted thresholds over time in light of additional information and changing circumstances, held orders that exceeded thresholds for further review, and released orders only after a determination was made that orders were not suspicious.

In May 2008, Cardinal submitted to DEA a "now and then" chart that describes the changes that Cardinal had made to its anti-diversion program since December 2007.[142] The chart indicates that Cardinal had expanded its SOM personnel and put into place an "[e]lectronic system to identify, block, and report sales of controlled substances to retail independent customers based upon a pre-determined monthly threshold for 102 controlled substance families."[143] The blocked orders were "analyzed by professional anti-diversion staff members with pharmacy, prosecutor, and/or law enforcement experience."[144] The chart states that "KYC [Know Your Customer] due diligence, pharmacy site visits, and other investigative processes may be employed to determine whether quantities ordered are legitimate."[145] The chart also describes the mandatory site visits "to assess compliance."[146] Further, SOM pharmacist Chris Forst testified that, when he joined QRA in February 2008, a system was in place in which "a list of customers that exceeded their threshold values … was generated each night. Each customer was reviewed, looking at different aspects of the customer, where they were located, relevant information like their ordering patterns, et cetera, et cetera, and the orders were either released or cut or cut and reported as suspicious, depending on the circumstance."[147] When Forst arrived, there were thresholds assigned to all customers, including chain pharmacies.[148] Forst also testified that, when he arrived, "[t]here were policies and procedures in place, and there were rough drafts of new ways that we were going to be doing things that were in place."[149] He also testified that there were

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[141] *Id.*

[142] CAH_MDL2804_02156858 (attaching CAH_MDL2804_02156859); *see also* Outline of Key Actions on Anti-Diversion (Jan. 11, 2007), CAH_MDL_PRIORPROD_DEA07_00968292 (contains more details regarding the implementation of these changes).

[143] CAH_MDL2804_02156859, at 859-860.

[144] *Id.* at 861.

[145] *Id.* at 862.

[146] *Id.* at 863.

[147] Chris Forst Deposition Tr. 34:17-35:5.

[148] *Id.* at 38:4-22.

[149] *Id.* at 36:21-37:12.

continuous changes occurring such that "the policy would change daily, weekly, monthly as we focused on what we needed to be looking for."[150]

Know Your Customer ("KYC")

Evidence shows that in January 2008, Cardinal issued a standard operating procedure regarding review of potential customers, and updated this procedure over time.[151] Consistent with the focus on retail independents in the ABDC presentation, the initial procedures required completion of a "Know Your Customer" questionnaire for new retail independent customers, which required information about the pharmacy's business such as licensing, disciplinary actions, and the pharmacy's usage for certain products; required interior and exterior photos to be taken of the pharmacy; and required all new retail independent customers to sign a DEA compliance agreement.[152] The anti-diversion group reviewed and analyzed potential customers, including review of the questionnaires to verify the information provided by the customer, and to look for common indicia of diversion.[153] If there were any concerns, a pharmacist in the anti-diversion group would review the data on the potential customer and decide whether to open the account, refer the case for additional investigation, or decline the account.[154]

Moné's Declaration further describes Cardinal's processes for new chain customers. It would obtain information regarding the chain as a corporate entity, including the chain's number of stores, anticipated usage, and internal anti-diversion procedures.[155] If a chain sought to open a new pharmacy, the corporate office would need to provide Cardinal with the new pharmacy's state license and DEA registration.[156]

As to Cardinal's KYC system, Rafalski concluded that "Cardinal Health failures came not necessarily in the design of its KYC system but in the operation of the system," and that Cardinal

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[150] *Id.* at 37:10-12. Rafalski's statement about the absence of information on the evolution of Cardinal Health's SOM program during this timeframe is incorrect. Rafalski report 48. He quotes the early testimony of Cardinal Health's corporate representative to state that "Cardinal does not know what changes it made within its SOM systems from September 2006 through at least late 2007," but Cardinal Health supplemented its explanation of that timeframe in written testimony from its corporate representative, and these changes are also reflected in other testimony and documents discussed herein. *See* Cardinal Health's Revised and Supplemental Response to 30(b)(6) Notice 1, Topic (a).

[151] *See* 2008.01.04 - New Retail Independent Customer Survey Process SOP (Jan. 4, 2008), CAH_MDL_PRIORPROD_DEA07_00891019; *see also* New Account Approval SOP (Dec. 22, 2008).

[152] *Id.*

[153] *Id.*; *see also* Moné Declaration ¶ 12; Nicholas Rausch Declaration ¶ 11 (Apr. 13, 2012), CAH_MDL_PRIORPROD_DEA12_00000534; Doug Emma Deposition Tr. 51:2-51:15.

[154] Moné Declaration ¶ 12.

[155] *Id.* ¶ 13-14; Rausch Declaration ¶ 14-15; Doug Emma Deposition Tr. 51:2-51:15.

[156] *Id.*

did not "maintain" sufficient due diligence files on each of its customers.[157] I disagree. In my opinion, Rafalski is inappropriately relying upon what he contends is the absence of documentation, more than a decade later in some cases, of the due diligence Cardinal conducted on its customers. But as discussed elsewhere in the Report, there is no regulatory requirement that a registrant document due diligence of their customers at all, let alone to maintain that documentation for a decade or more after-the-fact. Given the passage of time and the absence of any requirement to document these actions in the first place, one cannot reliably reach the conclusions Rafalski is drawing.

In addition, and contrary to Rafalski's assertion, documents and testimony show that Cardinal followed its procedures by holding orders that were identified by the thresholds set for its customers, and released those orders (if at all) only after a decision that the order was not suspicious. For example, I have reviewed a spreadsheet identifying a subset of those held orders for Summit and Cuyahoga Counties.[158] Although the same records are not available for all time periods, testimony corroborates that this type of diligence occurred in the regular course of business.[159] I have also reviewed the Supplemental Report of John MacDonald, which presents statistics on the number of orders held, and then subsequently cut or released in Summit and Cuyahoga Counties from 2010-2018. Those figures show that Cardinal held 418 orders in Summit and Cuyahoga Counties during the time period. 43% of the held orders were cut and not shipped, and 57% were released for shipment.[160] Those figures corroborate that Cardinal was appropriately exercising judgment in accordance with its procedures.

Rafalski also concludes that Cardinal "relied on chain customers to conduct their own due diligence and investigations," citing to the Declaration of Michael Moné.[161] Rafalski is taking that statement out of context. Moné made clear in that same declaration that when a threshold event involving a chain pharmacy store occurred, the customer's account manager would contact the chain's corporate office to request information regarding the order at issue, and then provide that information to the anti-diversion group for review.[162] That contradicts Rafalski's assumption that Cardinal did not conduct its own evaluation of these orders. In addition, in my opinion there is nothing improper or unreasonable in Cardinal seeking information from chain corporate offices, rather than from individual stores. In my experience, DEA Diversion Investigators do the same per corporate guidelines when seeking information about a pharmacy within a corporate chain, for example, when requesting prescription profiles on practitioners.

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[157] Rafalski Report 66.

[158] *See* Spreadsheet Containing Held Orders in Cuyahoga and Summit Counties, November 22, 2010, to April 16, 2018, CAH_MDL2804_00135242.

[159] Shirlene Justus Deposition Tr. 20:13-21:4, 39:11-40:3, 88:14-103:16; Chris Forst Deposition Tr. 131:7-11; Doug Emma Deposition Tr. 14:15-14:22.

[160] Supplemental MacDonald Report 1-2.

[161] Rafalski Report 66.

[162] Moné Declaration ¶ 19.

Further, there are no regulatory provisions specifying correct or incorrect ways for registrants to know their customers. At the September 2007 meeting with the industry, DEA provided examples of what a wholesale distributor should do to know their customer and what to look for.[163] For example, they mentioned inspecting pharmacies. They also mentioned such actions as "doing Google searches" to determine if the pharmacy's name was affiliated with an internet site and getting information from the state as to the nature and manner of prior legal actions against a pharmacy. And they gave a checklist of "Internet Pharmacy Decision Questions" meant as a guide. These are all consistent with the KYC system that Cardinal had in place during this time period.

Electronic monitoring

In December 2008, Cardinal issued a series of additional SOPs regarding its SOM program, which also were updated over time. The documents reflect that Cardinal worked closely with compliance consultant Dendrite/Cegedim/Buzzeo to develop these SOPs and to enhance Cardinal's SOM program.[164]

One SOP details how thresholds were calculated: (1) extract and formulate list of customers that have purchased monitored items and historical sales data for those items; (2) differentiate customers through segmentation by size and/or specialty; (3) evaluate historical controlled substance sales data per drug family, per month, for each customer segment to establish appropriate threshold limits, using multipliers of 3, 5, or 8; (4) incorporate Know Your Customer information about the pharmacies to establish final threshold limits, and (5) adjust for standard package sizes, and finalize threshold limits.[165] Thresholds for new chain stores were based on a threshold for the entire chain, and took into account the chain's anti-diversion measures.[166]

There is no basis for Rafalski's assertion that Cardinal's approach to setting thresholds during this time was "fatally flawed."[167] As discussed throughout this report, nothing in the CFR, in DEA communications with registrants, or in the applicable portions of the Diversion Investigators' Manual used by DEA Diversion Investigators, establishes that there is any "correct" or "incorrect" design of a suspicious order monitoring system generally, or these sorts

[163] CAH_MDL_PRIORPROD_DEA07_01198345, at 346.

[164] CAH_MDL_PRIORPROD_DEA07_02739847 (proposed scope of work by Dendrite); CAH_MDL_PRIORPROD_DEA07_00870163 (chart identifying various action items); CAH_MDL2804_02576927 (describing Dendrite support on "many fronts (pharmacy onsite reviews), [and] calls to [customers]").

[165] Process to Establish SOM Threshold Limits SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0005610, at 610-613.

[166] Moné Declaration ¶ 17; Rausch Supplemental Declaration ¶ 5 (Apr. 23, 2012), CAH_MDL_PRIORPROD_DEA12_00007820.

[167] Rafalski Report 62.

of thresholds specifically. As I have discussed, DEA did endorse the concept of using thresholds in its approval of the ABDC system upon which Cardinal's own system was in part based. Nothing at all supports Rafalski's position that any particular threshold within such a system can be assessed as "fatally flawed" because it used, for example, one multiplier instead of another. The objective of identifying orders that are "unusual" based on what a distributor knows about the particular customers placing those orders, inherently requires the exercise of judgment in a way that cannot be correct or incorrect in the manner Rafalski is suggesting. As discussed above, at the time these systems were being developed, DEA told the industry that there is no requirement that all distributors use identical systems.[168] In a 2012 Memorandum of Agreement with Cardinal, DEA stated that it "does not endorse or otherwise approve threshold procedures[.]"[169] In 2015, the then-head of DEA's Diversion Control Division responded to concerns raised by the Government Accountability Office (GAO) about DEA's lack of guidance on threshold setting, and stated: "DEA cannot direct how distributors conduct their businesses, including the amount of controlled substances lawfully distributed or dispensed to customers, i.e., pharmacies and practitioners."[170] As a result, Rafalski's opinion that Cardinal set incorrect thresholds has no objective basis.

In addition to the above material, nothing in the training I received as a DEA Diversion Investigator, or in the curriculum that we used to instruct DEA Diversion Investigators during the time that I was Unit Chief of the Training Division (immediately prior to when Rafalski received his own training), supports Rafalski's conclusions about thresholds. Instead, the principles we taught would lead to the conclusion that thresholds which had been adopted in good faith based upon a registrant's knowledge of its customers, were fully compliant with its obligations under the CFR. In my opinion, by second-guessing the levels at which individual thresholds were set by a distributor, Rafalski is applying a type of analysis that Diversion Investigators are not trained to conduct, and that they do not conduct in the ordinary course of their investigations on behalf of DEA. In short, Cardinal's threshold system and use of multipliers are reasonably designed to comply with its regulatory obligations.

Another SOP provides details review of threshold events.[171] As the SOP states, when there is a threshold event, the order is held and the reviewing pharmacist must determine if the order is "reasonable" based on relevant information.[172] In review of a held order, if the order is deemed

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[168] CAH_MDL_PRIORPROD_DEA07_01198345, at 346-347.

[169] Administrative Memorandum of Agreement Between DEA and Cardinal (May 2012), CAH_MDL2804_02213664, at 666.

[170] U.S. Government Accountability Office, "More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access" (June 2015) at 77 (May 29, 2015 Letter from Joe Rannazzisi to Linda Kohn).

[171] Threshold Event Review, Self Verification; Decision Making and Threshold Outcome Communication SOP (Nov. 5, 2009), CAH_MDL_PRIORPROD_AG_0005229.

[172] *Id.*

reasonable it is released, and if it is unreasonable it is cut.[173] Forst was a pharmacist who began at Cardinal in February 2008 and was responsible for "[d]etecting and reporting suspicious orders and responding to threshold events.[174] He affirmed that "no order is going to go out of Cardinal that's hit a threshold without somebody looking at it, reviewing it, and releasing it."[175]

Testimony shows that in the review of a threshold event, a pharmacist would review information from various sources, and use their professional experience to make a judgment.[176] In 2010, Cardinal created and implemented the Anti-Diversion Centralization (ADC) system, a central repository that allowed the previously separate data to be stored and accessible on a single platform during review of a threshold event.[177] During a threshold event review, a pharmacist would review both the information that Cardinal maintained on its customers, such as the customer's purchasing history, as well as information that a pharmacist could obtain, such as by calling the pharmacy or searching online.[178] For example, if an online search revealed the presence of one large medical hospital in a relatively small area, that could increase the expected patient population of a nearby pharmacy.[179]

Rafalski is incorrect when he states that "Cardinal Health's productions demonstrate that it regularly ignored the thresholds it had set for its customers."[180] He points to examples where orders exceeded thresholds and were reviewed and released. This simply reflects that a pharmacist reviewed the order and determined that it was reasonable, consistent with the controlling SOP; it does not show that the pharmacist "ignored" the threshold. As Rafalski later concedes, an above-threshold order would only be sent if "it was reviewed by a Cardinal Health employee and a conscious decision was made to release the order that exceeded the threshold."[181] In my opinion, that process is entirely reasonable and consistent with Cardinal's duties under the CFR.

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[173] *Id.*

[174] Chris Forst Deposition Tr. 148:21-149:4.

[175] *Id.* at 131:7-131:11; Cardinal Health DEA Compliance Presentation, CAH_MDL2804_00618705, at 758-760.

[176] Shirlene Justus Deposition Tr. 20:13-21:4, 39:11-40:3, 88:14-103:16; Kimberly Howenstein Deposition Tr. 57:17-58:17; Moné Declaration ¶¶ 19-20.

[177] Moné Declaration ¶ 30.Chris Forst Deposition Tr. 164:5-164:23; Doug Emma Deposition Tr. 23:4-23:10.

[178] Chris Forst Deposition Tr. 173:17-174:2, 191:16-191:21; Doug Emma Deposition Tr. 125:9-125:13.

[179] Doug Emma Deposition Tr. 119:22-120:2, 124:21-124:24.

[180] Rafalski Report 62.

[181] *Id.* at 65.

Rafalski also asserts without adequate basis that the practice of allowing customers to exceed their thresholds is a "systemic" problem.[182] Rafalski points to DEA enforcement actions encompassing shipments to a limited number of pharmacies in Maryland and Florida during discrete time periods to support that statement. But that does not evidence a "systemic" problem at all, let alone one that has connections to Cuyahoga or Summit Counties. In my experience, DEA enforcement actions would not focus upon a limited number of specific pharmacies in one part of the country if there was evidence of non-compliance systemically throughout the country. As discussed above, each distribution center used by Cardinal for the delivery of pharmaceuticals is its own registrant, and each would be subject to inspections by the DEA field office in its area. The only reasonable inference to be drawn from the fact that one field office pursued an enforcement action based upon shipments from the distribution center in its jurisdiction, while every other field office did not for the distribution centers in their jurisdictions, is that there is *not* a "systemic" problem of non-conformance with the CFR.[183]

Further, as to the four pharmacies at issue in the 2012 DEA action, Cardinal Health had already ceased distributing to both Caremed and Gulf Coast (on September 26, 2011 and October 5, 2011, respectively) prior to the issuance of DEA's Administrative Inspection Warrant ("AIW") for Cardinal's Lakeland, Florida distribution center on October 25, 2011.[184] As to the other two pharmacies at issue—two different CVS pharmacies in Florida—Rafalski focuses on CVS #219 and characterizes a slide deck sent to Gilberto Quintero as "'talking points' for the 'abnormal' buying pattern of CVS #219 in Sanford, Florida."[185] Quintero testified, however, that these slides were prepared in order to meet with CVS to address concerns by Cardinal.[186] Indeed, at Cardinal's request, CVS provided a written memo concerning the investigation that was performed, and Cardinal continued conducting additional due diligence of its own.[187] Rafalski also fails to identify anything connecting these Florida pharmacies to Summit or Cuyahoga Counties, and in my opinion they have no such connection.

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[182] *Id.* at 62.

[183] I have also reviewed the settlement agreements entered into by Cardinal to resolve the proceedings referenced by Rafalski. They also do not establish or support the existence of any "systemic" non-conformance with the CFR.

[184] Moné Declaration ¶ 49; Faxes from Michael Moné to DEA Field Offices and Florida Board of Pharmacy re Suspension of Controlled and Monitored Substances Sales to Caremed (Sept. 26, 2011), CAH_MDL_PRIORPROD_DEA12_00001934; Faxes from Michael Moné to DEA Field Offices and Florida Board of Pharmacy re Suspension of Controlled and Monitored Substances Sales to Gulf Coast (Oct. 5, 2011), CAH_MDL_PRIORPROD_DEA12_00001940; Administrative Inspection Warrant for Cardinal Health Distribution Center in Lakeland, Florida (Oct. 25, 2011), CAH_MDL_PRIORPROD_DEA12_00001950.

[185] Rafalski Report 63 (citing CAH_MDL_PRIORPROD_DEA12_00003244, 00003250; CAH_MDL2804_01103874, 01103875; CAH_MDL_PRIORPROD_DEA12_00014224 at 00014248 para 46).

[186] Gilberto Quintero Deposition Tr. 155:6-157:1, 165:2-167:20, 170:20-171:4.

[187] *Id.*

Site visits and investigations

Another set of SOPs provide details on site visits and investigations of customers. One SOP explains how an investigation of a customer can occur following a threshold event.[188] In the event of a site visit, the salesperson is notified and then QRA schedules a site visit within 5 working days, performs the visit, and collects relevant information.[189]

Another SOP details the procedures for on-site investigations, including how cases are assigned to investigators, and details on the four key aspects of each investigation: (1) initial case preparation, (2) background investigation, (3) site visit, and (4) preparation of reports.[190] The SOP outlines details and procedures for each of the four key steps, including specific directions regarding how to conduct the site visit itself, and details regarding what should be in the report, with references to a sample report.[191]

Morse, the Director of QRA Investigations during this timeframe, described the role of investigators as follows:

> Our role was to gather information that was reviewed by others. We would be trying to gather information about the pharmacy, including the size. We'd want to take a look at the pharmacy's location, what's the availability of healthcare physicians, prescribers. We'd want to take a look at the pharmacy's practices, the type of pharmacy; is it a specialty pharmacy, is it a clinic pharmacy, is it a community pharmacy with sundries and everything else. We'd want to take a look at, to the extent we can, who the patients are, and to the extent we can, where they come from.[192]

In addition to the investigations by QRA, evidence shows that salespeople were also tasked with monitoring their customers in what could be classified as site visits but also as part of the ongoing KYC process. In 2008, the sales force started receiving monthly "Highlight Reports" that identified "Red Flag" or "Yellow Flag" customers based on certain percentage increases in their controlled substance orders.[193] The Highlight Report SOP required salespeople to visit red flag customers within ten working days to look for signs of diversion and complete an online

[188] Sales – Investigation SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0029938.

[189] *Id.* at 940.

[190] On-Site Investigations SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0029468.

[191] *Id.* at 474-477.

[192] Steve Morse Deposition Tr. 98:23-99:14.

[193] Sales – Highlight Report SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0029955.

Customer Visit form, and to contact yellow flag customers as soon as possible to understand the reason for the increased ordering.[194]

A separate SOP issued in 2008 required salespeople to perform an "early dialogue" with customers whose orders neared their threshold, and document the relevant facts and complete a Customer Visit form.[195] An additional SOP made clear that salespeople were expected to visit their customers and look for signs of diversions at each visit—like those signals that investigators looked out for during full site visits—and required the salespeople to complete an online Customer Visit form and assess a risk level for the customer if two or more of those anti-diversion alert signals were present.[196] Ray Carney, a current Director for Retail Sales and former Sales Manager from 2000 to 2010, confirmed the types of things that, "[i]n addition to the work of the QRA anti-diversion team," his sales team does to try to prevent diversion: "We act as the eyes and ears of the company on the ground to report up any unusual or out of the ordinary activity that we see or witness at a pharmacy location."[197]

Rafalski acknowledges that during this timeframe, "there was clearly some due diligence being conducted, some of which occurred in the way of on-site investigations," but then mischaracterizes the 2013 Special Demand Committee Report of Cardinal's Board of Directors as finding that "those investigations were not being reviewed properly."[198] The 2013 report does not support Rafalski's characterization. It explains that after initially reviewing all site visit reports, Morse subsequently modified the procedure by no longer personally reviewing reports for pharmacies identified as "low risk" while continuing to review all of those classified as "medium" or "high" risk.[199]

Rafalski also criticizes Cardinal for its differing treatment of retail independent pharmacies and chain pharmacies.[200] As discussed previously, at a September 2007 industry conference, DEA identified as the "new industry standard" an SOM system that was described publicly as having exempted chain pharmacies from the "Know Your Customer" due diligence procedures.[201] However, Cardinal procedures applied to both chain and independent retail pharmacies. Cardinal did, however, reasonably take into account the anti-diversion policies and procedures

[194] *Id.* at 957.

[195] Sales – Early Dialogue SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0029952.

[196] Sales – Anti-Diversion Alert Signals SOP (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0029945.

[197] Ray Carney Deposition Tr. 219:2-219:9.

[198] Rafalski Report 53.

[199] CAH_MDL_PRIORPROD_HOUSE_0003331, at 352.

[200] Rafalski Report 52-53, 54, 65-66.

[201] CAH_MDL_PRIORPROD_DEA07_01198345, at 351.

that those chain pharmacies had implemented.[202] With respect to CVS, Cardinal obtained information from CVS's loss prevention department, in addition to the information that Cardinal itself had, with respect to concerns identified in CVS's orders or stores.[203] Moné states that he discussed this practice with DEA officials Michael Arpaio and Barbara Boockholdt, asked them whether DEA had any concerns, and that they did not identify any issues.[204] In my opinion, that treatment of chain pharmacies was reasonable and appropriate under prevailing industry standards at the time.

* * *

Evidence shows that, over time, Cardinal has attempted to modify and improve their due diligence, in the form of the "Know Your Customer" program, setting of thresholds, monitoring of threshold events, site investigations, and various other aspects of the company's suspicious order monitoring program.

As discussed above, evidence also shows that Cardinal provided extensive training on these programs and its SOM program in general.[205] Cardinal also provided its sales personnel (known as Pharmacy Business Consultants, or PBCs) with training on the Know Your Customer procedures and the electronic monitoring system, as well as training on various indicia of diversion.[206] In my opinion, these actions are consistent with a good faith attempt to implement appropriate procedures to identify suspicious orders and maintain controls against diversion.

Evidence similarly shows that Cardinal conducted reasonable diligence on its customers throughout the SOM process. As Forst testified:

> I can say with the system that we used, we did as much due diligence on our customers there that we could. And, again, some customers were large customers and required more medications than other customers, based on their proximity, based on the proximity of like hospitals around them, based on proximity of what type of physician practices were there. We sent out investigators to check out the ones that were like higher volumes to make sure that there was no signs of diversion going on, according to the list of what you're looking for signs of diversion. We went back several times to double check to make sure that if we missed something, that we would catch up on it. We asked for more information for those customers. Not that we didn't ask for information across the board … but if it was something

[202] Moné Declaration ¶¶ 10, 19; Rausch Deposition Tr. 182:12-183:10.

[203] Moné Declaration ¶ 29.

[204] *Id.*

[205] Craig Morford Declaration ¶ 8 (Apr. 12, 2012), CAH_MDL_PRIORPROD_DEA12_00000560; Gilberto Quintero Declaration ¶ 8 (Apr. 13, 2012), CAH_MDL_PRIORPROD_DEA12_00000518.

[206] Jon Giacomin Declaration ¶¶ 9-10, CAH_MDL_PRIORPROD_DEA12_00000553.

> in an area that we focused on, we tried to do the best that we could do to evaluate each and every pharmacy that we served.[207]

In my opinion, Rafalski is incorrect when he states without support that "Cardinal Health provided almost preferential treatment to its chain pharmacies/national accounts as compared to their retail independent customers;" as he then acknowledges, "Cardinal Health's policies did not reflect this almost preferential treatment."[208] Cardinal did have different policies for its retail independent pharmacies, but the evidence does not support the conclusion that their policies were "preferential" or insufficient.

D. Opinion: Further Enhancements of Cardinal's SOM from 2012 to Present Were Consistent with DEA Expectations, Industry Standards, and Prevailing Practice

In my opinion, Cardinal appropriately continued to make modifications to its SOM system over time. These modifications evidence a good faith effort to meet DEA's evolving expectations concerning anti-diversion. Cardinal's policies and procedures from this time period complied with DEA's regulations and expectations and industry standards.

In May 2012, DEA and Cardinal entered into Memorandum of Agreement. The 2012 Agreement identified specific terms and conditions Cardinal was to follow with regard to its suspicious order monitoring system and "Know Your Customer" program. Unlike its previous position of not approving or endorsing how a registrant implemented these programs, DEA and Cardinal agreed Cardinal would follow a specific protocol as detailed in the Agreement.[209]

Evidence shows that Cardinal has continued to enhance its SOM system and, in my opinion, these modified systems are reasonable and remain in compliance with Cardinal's obligations under the CFR. In July 2013, Cardinal issued an updated standard operating procedure regarding review of potential customers, and continued to update this procedure over time.[210] This new account setup procedure emphasized the potential customer's historical purchasing behavior.[211] The Cardinal Pharmaceutical Distribution sales team and the QRA Account team are responsible for various aspects of new customer document collection, vetting and onboarding.[212] The QRA Account Setup team verifies all appropriate documentation is in order, conducts a thorough review of the proposed customer, and will only approve sales of controlled substance products if

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[207] Chris Forst Deposition Tr. 258:18-259:16.

[208] Rafalski Report 52-53.

[209] Administrative Memorandum of Agreement Between DEA and Cardinal (May 2012), CAH_MDL2804_02213664, at 665-668.

[210] New Account Approval SOP (July 18, 2013), CAH_MDL_PRIORPROD_AG_0029620.

[211] Know Your Customer Survey (June 2013), CAH_MDL2804_03063381.

[212] *Id.*; New Account Approval SOP (July 18, 2013), CAH_MDL_PRIORPROD_AG_0029620.

the customer is not determined to pose an unreasonable risk for diversion.[213] If red flags are identified, QRA may request additional supporting information and/or may engage the QRA pharmacist team to assist with the review.[214] In 2014 and 2015, Cardinal updated its new account approval process to add procedures for handling suspected criminal activity by potential customers and to require peer review of a random sampling of accounts that were approved the previous month to ensure the due diligence review process was completed correctly.[215]

Cardinal continues to utilize an appropriate threshold system to detect and report potentially suspicious orders. In 2013, Cardinal enhanced its threshold-setting methodology.[216] Thresholds are calculated based on the appropriate class of trade.[217] Thresholds are set base [redacted] and other factors that have evolved and been enhanced over time.[218]

Rafalski asserts that Cardinal "now based the thresholds solely on the individual customer's information without consideration for the population that it served or comparison to similar customers."[219] That is incorrect and contrary to the evidence. As discussed in the preceding paragraph, thresholds are set [redacted] does not contradict anything in Cardinal's policies, or any obligations imposed by 21 CFR 1301.74(b).

Beginning in February 2013, Cardinal introduced additional criteria to its threshold calculation methodology.[221] These factors include [redacted];

[213] New Account Approval SOP (July 18, 2013), CAH_MDL_PRIORPROD_AG_0029620, at 625.

[214] *Id.* at 625-629.

[215] New Account Approval SOP (Nov. 17, 2014), CAH_MDL_PRIORPROD_AG_0029723; New Account Approval SOP (Jan. 21, 2015), CAH_MDL_PRIORPROD_AG_0029738.

[216] Letter from Todd Cameron, "Enhancing our anti-diversion program" (Jan. 23, 2013) CAH_MDL2804_02842789.

[217] Todd Cameron Deposition Tr. 167:12-16.

[218] CAH_MDL2804_02842789; Todd Cameron Deposition Tr., 44:12-21; 54:21-59:18; 137:11-140:20.

[219] Rafalski Report 66.

[220] Letter from Todd Cameron, "Enhancing our anti-diversion program" (Jan. 23, 2013) CAH_MDL2804_02842789; *see also* QRA SOM Customer Analytics: General Work Instructions (Apr. 24, 2017), CAH_MDL2804_00124903, at 903-912.

[221] CAH_MDL2804_02842789.

[redacted].[222]

In April 2012, Cardinal issued an updated standard operating procedure regarding detecting and reporting suspicious orders and responding to threshold events, and continued to update this procedure over time.[223] The continued refinement of these procedures evidences Cardinal's shift towards more objective evaluation. Pursuant to these updated procedures, any above-threshold orders are automatically held and are subject to review and consideration by Cardinal's QRA professionals.[224] Therefore, if a customer reaches a threshold in a drug family the customer will not receive any more of that drug family during the remainder of the customer's accrual cycle unless QRA determines that an increase in the customer's threshold is warranted.[225] [redacted][226]

Rafalski acknowledges that Cardinal did halt shipment of the orders which it identified as suspicious during this period.[227] However, he provides no basis for his further assertion that "Cardinal Health continued to ship base code 9143 and 9193 to the same registrant after reporting a suspicious order."[228] As noted in the expert report and supplemental report of John MacDonald, which I have reviewed, Rafalski has overlooked a number of legitimate explanations for the subsequent orders he identified, including that they arose in a new accrual cycle (where it would be appropriate to have shipped them, even if the limit for the previous cycle had been reached), or that the subsequent orders were of a smaller size and did not cause a limit to be reached. Based upon the data identified in MacDonald's report and supplement, I agree that Rafalski's criticism of those shipments is unfounded and does not suggest a failure to maintain effective controls against diversion.

Orders that do not exceed thresholds are subject to a "second level check" by distribution center staff, who may flag an under-threshold order for further review by QRA.[229] No above-threshold

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[222] *Id.*

[223] Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0001695; Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Oct. 17, 2016), CAH_MDL_PRIORPROD_AG_0004767.

[224] CAH_MDL_PRIORPROD_AG_0001695; CAH_MDL_PRIORPROD_AG_0004767.

[225] Letter from Todd Cameron, "Enhancing our anti-diversion program" (Jan. 23, 2013) CAH_MDL2804_02842789.

[226] Todd Cameron Deposition Tr. 52:23-53:5.

[227] Rafalski Report 69.

[228] *Id.*

[229] Todd Cameron Deposition Tr., 275:13-276:2.

order, or other flagged order, is released without QRA review.[230] Any orders determined to be suspicious by QRA professionals are promptly reported to DEA.[231]

A letter produced by Cardinal indicated that, as a result of an IT glitch, a small percentage of orders that exceeded Cardinal's thresholds, primarily for sub-base codes, were inadvertently not reported to DEA.[232] None of these orders shipped to any customer. The vast majority of the unshipped orders were from 2012 to 2015.[233] Cardinal utilized [redacted].[234] Only four of these unshipped orders would have been for customers in Cuyahoga and Summit Counties.[235] Cardinal learned of this glitch in 2018, and communicated it promptly to DEA with an offer to report those orders as suspicious.[236]

The evidence shows that in addition to the processes just discussed, Cardinal also maintains various data sources, internal systems, and other investigative tools available to QRA professionals. These tools are available to help QRA professionals carry out reviews of specific customers and make determinations about whether individual orders should be reported as suspicious and not shipped, and whether thresholds should be changed. The extent of a specific review is determined by the unique facts and circumstances of each matter.[237] While some new systems have come online and some have been retired during the 2012-2018 time period, available data sources and investigative tools have included the following:

1. Anti-Diversion Centralization (ADC): "Case management system used to facilitate the evaluation and assessment of threshold events, which are orders for controlled substance products held by the System Suspicious Order Monitoring (SOM) program. The case management system also allows members of Corporate Quality and Regulatory Affairs to reference customer specific

[230] *Id.*; Chris Forst Deposition Tr. 131:7-111.

[231] Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0001695; Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Oct. 17, 2016), CAH_MDL_PRIORPROD_AG_0004767.

[232] Letter from Larry Cote to Tom Prevoznik (June 1, 2018), CAH_MDL2804_02101803; Letter from Larry Cote to John Martin (Apr. 25, 2018), CAH_MDL2804_02101802.

[233] CAH_MDL2804_02101802.

[234] Todd Cameron Deposition Tr., 129:7-130:10

[235] Cardinal Health's Second Supplemental Written Response to Topic 16 in Plaintiffs' Second Notice of Deposition Pursuant to Rule 30(b)(6), at 4.

[236] *See* CAH_MDL2804_02101802; CAH_MDL2804_02101803.

[237] Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0001695.

information, as well as make adjustments to threshold limits and restrict customers from purchasing controlled substances."[238]

2. Distrack: Contains information related to customer thresholds and threshold events.[239]

3. Tableau files: Software tool that allows user to view analytical data and visualizations in interactive format, including purchase trend data.[240]

4. Content Navigator: Centralized document retention system for customer specific documents.[241]

5. Know Your Customer (KYC) Questionnaires: Survey used to collect information about Cardinal customers. The survey contains, among other items, questions specific to the customer's business model and controlled substance needs.[242]

6. Central Customer Database (CCDB): Cardinal system that stores customer data.[243]

7. Central Customer Database (CCDB) DEA Compliance Tool: Application used to restrict DEA numbers from purchasing controlled substance products.[244]

8. Site visits: Investigations can include on-site investigations, call surveys or surveillance visits.[245]

9. Other appropriate investigative methods including data requests, phone interviews, email interactions, and Internet searches.[246]

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[238] Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP (Oct. 17, 2016), CAH_MDL_PRIORPROD_AG_0004767.

[239] Todd Cameron Deposition Tr., 257:15-21; QRA Investigations SOP (Apr. 26, 2013), CAH_MDL_PRIORPROD_AG_0029220.

[240] QRA Investigations SOP (Apr. 26, 2013), CAH_MDL_PRIORPROD_AG_0029220.

[241] QRA Investigations SOP (Aug. 30, 2016), CAH_MDL_PRIORPROD_AG_0004773.

[242] New Account Approval SOP (Nov. 17, 2014), CAH_MDL_PRIORPROD_AG_0029723.

[243] *Id.*

[244] *Id.*

[245] Large Volume – Tactical and Analytical Committee Periodic Review Process SOP (Aug. 30, 2016), CAH_MDL_PRIORPROD_AG_0004806.

[246] On-Site Investigations SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0029127; Todd Cameron Deposition Tr. 247:17-22.

These data sources and investigative tools are used for a variety of QRA functions, including detecting and reporting suspicious orders, evaluating threshold events, and evaluating and adjusting thresholds.[247] QRA professionals also utilize other available data sources and investigative tools as appropriate. For example, when evaluating and adjusting thresholds pursuant to a Working Guideline issued in January 2013, QRA professionals [redacted] and various other information as relevant.[248]

On site investigations are conducted pursuant to requests by QRA, LV-TAC (described more fully below), and the Controlled Substance Regular Purchaser Periodic Review Process, or from other Cardinal business units or the ethics and compliance hotline.[249] Cardinal's procedures for investigations are intended to comply with, among other things, 2012 DEA guidance.[250] In April 2012, Cardinal issued an updated standard operating procedure regarding on-site investigations, and continued to update this procedure over time.[251] [redacted].[253] [redacted].[254] Investigators would then document the report, analyze and make a final assessment.[255] Cardinal later updated its on-site investigation procedure to include, in addition to these standard on-site investigations, additional surveillance visits and customer call surveys.[256] Surveillance visits, more limited in scope,

[247] *See* SOPs cited in the preceding footnotes.

[248] QRA SOM Customer Analytics: General Work Instructions (Apr. 24, 2017), CAH_MDL2804_00124903.

[249] Todd Cameron Deposition Tr., 278:6-9; On-Site Investigations SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0029127.

[250] QRA Investigations SOP (Apr. 26, 2013), CAH_MDL_PRIORPROD_AG_0029220.

[251] On-Site Investigations SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0029127; QRA Investigations SOP (Apr. 26, 2013), CAH_MDL_PRIORPROD_AG_0029220; QRA Investigations SOP (Aug. 30, 2016), CAH_MDL_PRIORPROD_AG_0004773.

[252] On-Site Investigations SOP (Apr. 12, 2012), CAH_MDL_PRIORPROD_AG_0029127.

[253] *Id.*

[254] *Id.*

[255] *Id.*

[256] On-Site QRA and Surveillance Investigations (June 6, 2012), CAH_MDL_PRIORPROD_AG_0029155.

sought to identify visible signs of diversion via unannounced visits at DEA registered locations.[257]

In 2012, pursuant to the DEA MOA, Cardinal created the Large Volume – Tactical and Analytical Committee ("LV-TAC") periodic review process, and continued to follow this procedure over time.[258]

This committee functions to "identify and periodically assess the top retail purchasers of commonly diverted controlled substances or other drugs of interest," including both chain and independent retail pharmacies, and may direct "QRA personnel to perform further due diligence."[259] "The purposes of the committee is to conduct a detailed review of these large volume accounts in order to evaluate the likelihood that a customer is engaged in Product Diversion based on 'red flags' identified by the … DEA and other known signs of product diversion."[260] The committee, after thorough review, decides whether to "continue or suspend the ability of these customers to purchase controlled substances from Cardinal Health" based on numerous factors which are considered to "assess the risk of product diversion."[261] The committee considers "purchase trend data," "investigative reports," and "other information as required."[262]

Todd Cameron, who led Cardinal's QRA team during this period, participated in meetings at DEA headquarters in 2015 and 2016.[263] Cameron testified that these meetings were so that Cardinal could "show [its] anti-diversion program to DEA, make them aware of … how we were doing the things that we were doing, and talk to them about understanding the suspicious orders that would be coming from us. And then have conversations about trying to have collaborative discussions to help both of us in controlling diversion."[264] Cameron testified that Cardinal got feedback from the DEA during these meetings, including that DEA representatives "told [Cardinal] that we were looking at all the right components and looking at them in the right manner to run an anti-diversion program."[265] Cameron also traveled to and met with individuals

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[257] *Id.*

[258] Todd Cameron Deposition Tr. 254:6-23; Large Volume – Tactical and Analytical Committee Periodic Review Process SOP (Aug. 30, 2016), CAH_MDL_PRIORPROD_AG_0004806.

[259] CAH_MDL_PRIORPROD_AG_0004806.

[260] *Id.*

[261] *Id.*

[262] *Id.*

[263] Todd Cameron Deposition Tr. 30:16-24.

[264] *Id.* at 31:5-12.

[265] *Id.* at 33:17-34:6.

at DEA field offices in this role.[266] Additionally, DEA performed cyclic investigations at Cardinal distribution centers throughout this period.[267]

In my opinion, the evidence discussed in this report shows that during the period this system was in place, Cardinal maintained effective controls against diversion and implemented a reasonable and appropriate SOM process consistent with 21 CFR 1301.74(b) and articulated DEA policies, standards, and regulations.

E. Opinion: The Expert Reports of James Rafalski and Seth Whitelaw Mischaracterize Cardinal's System and Cardinal's Relationship with Particular Customers

Rafalski's and Whitelaw's reports discuss due diligence conducted by Cardinal on specific customers in Cuyahoga and Summit Counties. Rafalski's report discusses CVS #3322 and New Choice Pharmacy,[268] and Whitelaw's report discusses CVS #3322 and CVS #4800.[269] The reports present an incomplete picture of the due diligence that Cardinal conducted on these pharmacies. The reports miss instances of due diligence contained within the customers' due diligence files, improperly discount the significance of the due diligence that is contained within the due diligence files, and ignore evidence of due diligence produced in this litigation but not contained in the due diligence files.

1. CVS #3322

Cardinal's due diligence file for CVS #3322 reflects Cardinal conducting thorough due diligence on the store. The file contains the following documents:

- June 11, 2012 – Report of Investigation.[270] This document describes a site visit that a Cardinal investigator conducted on CVS #3322. It says that Cardinal spent an hour looking for signs of potential diversion, including [redacted] These are appropriate red flags for a distributor to be looking for when evaluating whether a customer presents a risk of diversion. The information identified in the report does not indicate that the pharmacy posed a risk of diversion. The report also notes that the area in which the store was located "was moderately to heavy with vehicle traffic" and that the store had "a drive-thru window and is open 24-hours."

[266] *Id* at 37.

[267] *Id.* at 321.

[268] Rafalski Report 53-54.

[269] Whitelaw Report 51-52

[270] CAH_MDL2804_00000205.

- July 17, 2012 – Memo by Nicholas Rausch, Director, Regulatory Management, to File.[271] This memo summarizes data provided by CVS. The memo states, among other things, that the store had a monthly controlled substance prescription volume of less than 20%, that 3-6% of prescriptions were paid for in cash, and that 3-6% of controlled substance prescriptions were paid for in cash. These are appropriate data points for a distributor to consider when evaluating whether a customer presents a risk of diversion. In my opinion, these numbers do not suggest that the customer presented a risk of diversion.

- September 10, 2012 – QRA Survey and site visit.[272] This document indicates that, in response to a threshold event, Cardinal sent an investigator to conduct due diligence on CVS #3322. The survey contains questions that are appropriately geared toward identifying signs that a customer may pose a risk of diversion. The investigator's answers to the questions do not suggest that the customer presented a risk of diversion.

- January 19, 2014 – Surveillance Site Visit Report.[273] This report indicates that a Cardinal investigator conducted background research on the pharmacy and looked for facts that could present a red flag that the pharmacy may be engaged in diversion. The questions on the report are appropriated geared toward identifying signs that a customer might pose a risk of diversion. The investigator's answers to the questions do not suggest that the customer presented a risk of diversion.

- January 24, 2014 – Surveillance Site Visit Report.[274] This report is similar to the January 19, 2014 report, but was filled out by a different investigator.

- April 13, 2015 – Surveillance Site Visit Report.[275] This report is similar to the preceding Surveillance Site Visit Reports, but was filled out by a different investigator.

- April 27, 2015 – Memo from LV-TAC Committee to File.[276] This memo, approved by Todd Cameron, indicates that Cardinal made no changes to CVS #3322's thresholds.

- May 20, 2016 – Surveillance Site Visit Report.[277] This report is similar to the preceding Surveillance Site Visit Reports.

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[271] CAH_MDL2804_00000204.

[272] CAH_MDL2804_00000206.

[273] CAH_MDL2804_00000209.

[274] CAH_MDL2804_00000207.

[275] CAH_MDL2804_00000212.

[276] CAH_MDL2804_00000214.

[277] CAH_MDL2804_00000215.

- July 15, 2016 – Memo from Danielle Roberts to File.[278] This memo describes which products the store purchases from Cardinal. It notes, "No disproportionate growth within controlled/non-controlled ratio or within individual drug families." These facts are reasonable indicators for Cardinal to look to when evaluating whether to adjust thresholds for a customer.

- May 16, 2017 – Surveillance Site Visit Report.[279] This report is similar to the preceding Surveillance Site Visit Reports.

Both Rafalski and Whitelaw conclude that the information contained in Cardinal's due diligence file for CVS #3322 reflects inadequate due diligence. Rafalski states that "there is no documented due diligence prior to January 24, 2014."[280] As described above, the file contains a site visit report from June 11, 2012, a July 12, 2012 memo by Rausch, a September 10, 2012 QRA survey, and a January 19, 2014 site visit report, all of which pre-date January 24, 2014. These documents are all included within the set of documents that Rafalski identifies as Cardinal's due diligence file for CVS #3322.[281] Whitelaw acknowledges there was a site visit in June 2012, but appears to ignore the additional site visit conducted on September 10, 2012 and Rausch's July 17, 2012 memo. Both state, without providing any explanation, that the surveillance site visits are insufficient. This conclusion ignores the fact that the surveillance site visits capture information that is useful in identifying customers that could pose a risk of diversion. Based on my training and experience, these site visits are reasonable and appropriate, as is the documentation of them.

Neither Rafalski nor Whitelaw discuss the ratio of controlled to non-controlled substances and the cash-purchase ratio found in the due diligence files. Rafalski ignores this discussion entirely, while Whitelaw acknowledges that the reports contain "facts and figures" but does not address what they show.[282] Those "facts and figures" are a useful part of the due diligence process—such as the indication that less than 20% of CVS #3322's sales were for controlled substances, which suggests that CVS #3322 was within the expected range for a legitimate pharmacy. Likewise, the percentage of purchases in cash (3% to 6%) is a relevant factor for Cardinal to have considered, and shows that CVS # 3322 is within the expected range for a legitimate pharmacy.

Rafalski and Whitelaw also fail to acknowledge other documents that have been produced in this litigation that show that Cardinal conducted additional due diligence on CVS #3322, apparently solely on the basis that they were produced outside the confines of a folder entitled "due

[278] CAH_MDL2804_00000216.

[279] CAH_MDL2804_00000218.

[280] Rafalski Report 54.

[281] *See* Rafalski Report 54 n.184 (citing CAH_MDL2804_00000204-00000219 as the "CVS #3322 Due Diligence file").

[282] *See* Rafalski Report 53-54; Whitelaw Report 51.

diligence file." However, there is no regulatory obligation or other requirement on how documents of this nature should be filed or stored. As noted above, there is not even an obligation to retain such documentation, and those record-keeping obligations that do exist under the CFR are generally short, lasting only for two years. Evidence of actual due diligence cannot be disregarded on the basis of how the files were maintained, in whose custody they were found, or how long they were retained.

Among the documents contradicting Rafalski and Whitelaw's assertions about CVS # 3322 are the following:

- May 1, 2012 – Memo from Yingrui Liu Olesiuk, Advisor, Regulatory Management, Cardinal, to Michael Moné.[283] The memo "outline[s] findings and conclusions derived from data provided by CVS specific to store #3322." It provides a detailed review of the data specific to this store, looking at a number of factors that are very relevant to determining whether there was a risk that the store was engaged in diversion. The memo includes the following statements: [redacted]" In my opinion, all of these data points are indicative of a legitimate pharmacy that does not pose a risk of diversion.

- July 17–24, 2012 – Emails between Michael Moné, Nicholas Rausch, and Steve Morse.[284] These emails show that Moné requested the top ten purchasers of oxymorphone in Ohio, and then asked Morse to conduct site visits of the stores, which included CVS #3322.

- July 8, 2013 – Memo from Doug Emma, QRA Pharmacist, to LV-TAC Committee.[285] The memo "documents a Pharmacist's review of" CVS #3322. It provides data on prescriptions and concludes that the data shows that "combined Oxy/Hydro is approximately 6.7 percent" and that the store orders a "Broad mix of strengths." These are reasonable indicators for Cardinal to have looked at in conducting due diligence. These particular statistics do not indicate that CVS #3322 was engaged in diversion.

[283] CAH_MDL2804_02103920.

[284] CAH_MDL2804_01008818.

[285] CAH_MDL2804_02059277.

- April 2015 – LV-TAC Memo by Christopher Forst.[286] This memo indicates that CVS #3322 was being reviewed by LV-TAC because it purchased high volumes of oxycodone and hydrocodone combined. The review of the data indicates that oxycodone and hydrocodone combine to be 4.2% of all purchases by the pharmacy, which is within the range of normal purchases for a legitimate pharmacy. Attached to the memo is a snapshot of a screen from the Tableau software, which I have used. Tableau allows the user to evaluate numerous statistics for a particular customer. The inclusion of the snapshot in the memo demonstrates that Cardinal was looking at detailed data on CVS #3322 in conducting its due diligence on the store.[287]

These additional materials demonstrate that Cardinal conducted appropriate and reasonable due diligence on CVS #3322 at times that Rafalski and Whitelaw erroneously assert it had conducted no due diligence at all. It is my opinion that Cardinal's due diligence efforts with respect to these pharmacies met or exceeded its regulatory requirements, DEA expectations, as well as industry standards.

It is important to emphasize that neither Rafalski nor Whitelaw provide any facts indicating that CVS #3322 was engaged in diversion. The sole basis for Rafalski and Whitelaw addressing this store appears to be that it had high order volumes for hydrocodone and oxycodone.[288] But the due diligence documents put those high order volumes in context. The store ordered a high volume of non-controlled substances and controlled substances other than oxycodone and hydrocodone. Oxycodone and hydrocodone were a small share of the total volume of prescription drugs ordered by the store. Based on the due diligence documents, it is apparent that CVS #3322 is simply a store that fills a large number of all prescriptions. The share of those prescriptions that are for opioids is within the normal range for a pharmacy. Based on the information available to me, I see no information that would have led a reasonable distributor to cut off CVS #3322 from ordering opioids. In the materials described above, I see no information indicating that Cardinal ever failed to report a "suspicious order" of opioids to CVS #3322. Rafalski's and Whitelaw's focus on this pharmacy based upon its order volume also ignores that Cardinal since 2012 has had in place the LV-TAC process, which subjects high volume customers to additional review, and that process resulted in this store undergoing that review as documented above.

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[286] CAH_MDL2804_02477455. The memo does not have a date, but the Tableau snapshot that is attached to the memo shows data through April 2015. Additionally, I have been instructed by counsel that the metadata suggests that the document was created on April 24, 2015.

[287] The Tableau snapshot attached to the memo shows higher percentages of oxycodone and hydrocodone than 4.2%. That is not inconsistent with the findings in the memo. CVS stores ordered all of their schedule II products from Cardinal Health, and used Cardinal Health as a secondary distributor for other products. Memo from Danielle Roberts to File (July 15, 2016), CAH_MDL2804_00000216. The Tableau file appears to show certain statistics based only on Cardinal Health's own shipment data, while the 4.2% figure is based on total "store dispense information."

[288] Whitelaw also says that CVS #3322 "was double-dipping and ordering some of its hydrocodone supply (between 2 and 3%) from Cardinal." Whitelaw Report 51. There is nothing abnormal about CVS using Cardinal Health as a secondary supplier of hydrocodone. It is a common practice in the industry.

2. CVS #4800

The Whitelaw report also criticizes the due diligence that Cardinal conducted on CVS #4800.[289]

In discussing the produced due diligence file for CVS #4800, Whitelaw mentions an "undated questionnaire,"[290] a June 2012 site visit, and two surveillance site visits.[291] Whitelaw does not mention additional materials in the file, which include a July 17, 2012 memo from Nicholas Rausch stating that less than 20% of the total prescription volume at the store was controlled substances;[292] a September 11, 2012 QRA survey;[293] a November 15, 2013 memo from Todd Cameron reviewing data and stating that in the previous three months 17% of the store's prescriptions were controlled substances and 3.2% of scripts were paid for in cash;[294] a February 20, 2014 decision memo from the LV-TAC Committee;[295] and an April 14, 2016 Surveillance Site Visit Report.[296] For the reasons described in my discussion of the files for CVS #3322, these materials are appropriately designed to gather useful information for determining whether a customer poses a risk of diversion, and reflect that Cardinal in fact conducted reasonable and appropriate due diligence on CVS #4800. In my opinion, the data points reflected in these due diligence reports are indicative of a legitimate pharmacy that does not pose a risk of diversion.

There are also two "Anti-Diversion Early Dialogue Profile" documents for CVS #4800 not addressed by Whitelaw, one from June 22, 2010 and the other from July 21, 2010, which provide data on the pharmacy's purchases.[297] The documents indicate that Doug Emma reviewed the customer and decided not to adjust the threshold. These documents suggest that Cardinal was following its (now-retired) "Sales – Early Dialogue" SOP, which provided for fact-finding

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[289] Whitelaw Report 52.

[290] It is not clear what this refers to. I did not see an undated questionnaire in the produced due diligence file for CVS #4800, and Whitelaw did not identify such a document by bates number.

[291] Whitelaw Report 52 (citing Cardinal Health, Report of Investigation, (June 11, 2012), CAH_MDL2804_00000688; Cardinal Health, Surveillance Site Visit Report, (Jan. 24, 2014), CAH_MDL2804_00000690; Cardinal Health, Surveillance Site Visit Report (Jan. 20, 2014), CAH_MDL2804_00000692).

[292] CAH_MDL2804_00000687.

[293] CAH_MDL2804_00000689.

[294] CAH_MDL2804_00000694.

[295] CAH_MDL2804_00000695.

[296] CAH_MDL2804_00000696.

[297] Anti-Diversion Early Dialogue Profile (June 22, 2010), CAH_MDL2804_00540323; Anti-Diversion Early Dialogue Profile (July 21, 2010), CAH_MDL2804_00540324.

related to customer orders that were close to a threshold event but did not hit a threshold.[298] There is also an "Anti-Diversion Customer Profile" from July 29, 2010, which, like the Early Dialogue Profiles, provide data on CVS #4800's purchases.[299] This document indicates that Doug Emma reviewed the customer, cut a duplicate order, and did not adjust the customer's threshold. The document suggests that Cardinal was following its (now-retired) "Threshold Event Review, Self Verification; Decision Making and Threshold Outcome Communication" SOP, which provided for review of customer information in evaluating orders held for exceeding a threshold limit.[300]

Other materials outside the due diligence file show that Cardinal conducted a site visit of the store on January 9, 2014;[301] that Cardinal received data from CVS on the store's controlled to non-controlled ratio;[302] and that Christopher Forst, as part of LV-TAC Committee review of CVS #4800, considered that "Summa Akron City Hospital (voluntary non-profit) and several medical offices (orthopedics, sports medicine, dentistry, behavioral health, neurology and neonatology, etc.) are located within 1 mile," and reviewed the store's data on Tableau.[303]

These additional materials demonstrate that Cardinal conducted reasonable and appropriate due diligence on CVS #4800 that went well beyond what is described in Whitelaw's report. It is my opinion that Cardinal's due diligence efforts were reasonable and appropriate.

Whitelaw does not provide any facts indicating that CVS #4800 was engaged in diversion. He states that the store had high order volumes for hydrocodone and oxycodone, but the due diligence documents put those high order volumes in context. The store ordered a high volume of non-controlled substances and controlled substances other than oxycodone and hydrocodone. Oxycodone and hydrocodone were a small share of the total volume of prescription drugs ordered by the store. Based on the due diligence documents, it is apparent that CVS #4800 is simply a store that fills a large number of all prescriptions. The share of those prescriptions that are for opioids is within the normal range for a pharmacy. In the materials described above, I see no information that would have led a reasonable distributor to cut off CVS #4800 from ordering opioids. I see no information indicating that Cardinal ever failed to report a "suspicious order" of opioids shipped to CVS #4800. Whitelaw's focus on this pharmacy based upon its order

[298] Sales – Early Dialogue SOP (Dec. 12, 2008), CAH_MDL_PRIORPROD_AG_0029952.

[299] Anti-Diversion Customer Profile (July 29, 2010), CAH_MDL2804_00540322.

[300] Threshold Event Review, Self Verification; Decision Making and Threshold Outcome Communication SOP (Nov. 5, 2009), CAH_MDL_PRIORPROD_AG_0005229.

[301] CAH_MDL2804_01540111, at 119.

[302] Email from Bradley LeVay, CVS, to Nicholas Rausch and Yingrui Liu Olesiuk (April 10, 2013), CAH_MDL2804_00768525, attaching list of "detailed store summaries," CAH_MDL2804_00768526. The data for CVS #4800 shows that over a four-month period, the store had around 17% controlled substances and around 1% of controlled substances orders were paid for in cash. CAH_MDL2804_00768526, at 546.

[303] LV-TAC Memo by Christopher Forst (Feb. 7, 2014), CAH_MDL2804_01540111.

volume also ignores that Cardinal since 2012 has had in place the LV-TAC process, which subjects high volume customers to additional review, and that process resulted in this store undergoing that review as documented above.

3. New Choice Pharmacy

The Rafalski report also discusses another Cardinal customer, New Choice Pharmacy.[304] During the period that Cardinal distributed to New Choice, it was a hospital-owned pharmacy located within a hospital (Cuyahoga Falls General Hospital, which changed its name to Western Reserve Hospital). For some period of time, the hospital "established a significant Pain Management Clinic."[305]

As with the other pharmacies discussed above, Rafalski improperly discounts the significance of the due diligence materials located in the produced due diligence file for New Choice,[306] and did not consider further due diligence material.[307] This results in an incomplete and inaccurate picture of the due diligence that Cardinal conducted on New Choice. Michael Moné (a registered pharmacist, who, at the time, was the head of Cardinal's anti-diversion program) personally performed a site visit of New Choice on March 4, 2008.[308]

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[304] Rafalski Report 53.

[305] Memo from Michael Moné to File (Mar. 4, 2008), CAH_MDL2804_00834231, at 232; Letter from Summa Health System and Cuyahoga Falls General Hospital executives to Eric Brantley, Corporate Quality, Cardinal Health (Dec. 11, 2007), CAH_MDL_PRIORPROD_DEA07_01179513 (attaching materials showing that New Choice was owned by a hospital); Email from Kim Howenstein to Todd Cameron, et al. (Mar. 12, 2013), CAH_MDL2804_01695382 (stating that New Choice was "Owned by Summa Western Reserve Hospital").

[306] The produced due diligence file is CAH_MDL2804_00000605-CAH_MDL2804_00000634, CAH_MDL2804_00001518-CAH_MDL2804_000015140.

[307] Letter from Summa Health System and Cuyahoga Falls General Hospital executives to Eric Brantley, Corporate Quality, Cardinal Health (Dec. 11, 2007), CAH_MDL_PRIORPROD_DEA07_01179513 (attaching materials showing that New Choice was owned by a hospital); Email Chain re Order Limits on Hospital-Owned Pharmacies (Dec. 13, 2007), CAH_MDL_PRIORPROD_DEA07_00885842; Email from Halle Gay, Pharmacy Business Consultant, Cardinal Health, to Todd Cameron re On-Site Visit Request (Jan. 1, 2008), CAH_MDL_PRIORPROD_DEA07_00886767; Email from Halle Gay to Eric Brantley (Jan. 26, 2008), CAH_MDL_PRIORPROD_DEA07_02723885; Memo from Michael Moné to File (Mar. 4, 2008), CAH_MDL2804_00834231, at 232; Email Chain re Cut Order (May 17-18, 2009), CAH_M0L2804_00823568; Email Chain re New DEA Number (June 22, 2009), CAH_MDL2804_01705161; QRA Survey (Jan. 24, 2013), CAH_MDL2804_03082842; Email from Aimee Veliz, Manager, Regulatory Management, Cardinal Health, to LV-TAC Team (Feb. 18, 2013), CAH_MDL2804_02486337 (attaching printed Tableau files, CAH_ MDL2804_02486340, and New Choice memo, CAH_MDL2804_02486419); LV-TAC Memo (Feb. 19, 2013), CAH_MDL2804_03267318; Email Chain re Pharmacy Ownership (Mar. 12, 2013), CAH_MDL2804_01695382.

[308] Rafalski admitted at his deposition that he had not reviewed any materials related to Moné's visit to New Choice. James Rafalski Deposition Tr. 304:23-306:7.

The memo demonstrates that Moné conducted a thorough site visit that was appropriately designed to determine whether it was appropriate for Cardinal to continue shipping controlled substances in the amounts that were ordinary for New Choice. Among other findings, Moné documented that the pain management "program includes urines and other methodologies to validate appropriate controlled substance use. There was no evidence of internet activity and their security was substantial."[309] Based on the information reflected in the memo, Moné reasonably determined that it was appropriate for Cardinal to continue shipping controlled substances to New Choice.

Rafalski makes a number of statements about New Choice that are not supported by the due diligence materials that he cites and that I have reviewed. Rafalski suggests that Cardinal "fail[ed] to recognize risk factors that are apparent" before increasing New Choice's threshold on March 7, 2008. But the materials I have reviewed show that Cardinal was aware that New Choice was ordering a large volume of opioids and took appropriate steps to determine that the volume did not indicate that New Choice was engaged in diversion. Cardinal reviewed the potential risk factors and reasonably determined that the actual risk posed by New Choice was low. Additionally, the March 7, 2008 threshold increase for oxycodone came just three days after Moné conducted a thorough site visit, which indicated that Cardinal had the appropriate information to make the determination to increase the threshold.

Rafalski also says, "While New Choice was located in a medical complex, and for a time was owned by a hospital group, it did not service the hospital and instead actually serviced a pain clinic."[310] He does not provide a citation for this claim. Contrary to this assertion, Moné's site visit established that "[t]he pharmacy dispenses prescriptions written by the medical staff" of the hospital, "*most of whom* are ASAM and Pain Management Certified."[311] In addition, while Moné's memo states that New Choice "is located within a hospital that has an established Pain Management Clinic," nothing in the record that I have seen suggests that the pharmacy did not provide prescriptions to outpatients of the hospital generally.[312] In my experience, proximity to a hospital (or, as here, being on the grounds of the hospital complex) and proximity to medical practices specializing in the treatment of pain, are relevant to understanding the volume of controlled substances, including opioids, a pharmacy should reasonably be expected to dispense. Thresholds that take into account the legitimate differences between those pharmacies and other customers are reasonable and appropriate consistent with 21 CFR 1301.74(b) and DEA's "Know Your Customer" policy.

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[309] Memo from Michael Moné to File (Mar. 4, 2008), CAH_MDL2804_00834231, at 232.

[310] Rafalski Report 53.

[311] CAH_MDL2804_00834231, at 232.

[312] Rafalski also says that there is "no real explanation" in the produced due diligence file for New Choice changing its DEA number. But a produced email chain shows that at least one of the changes was due to a change in ownership. CAH_MDL2804_01705161

Rafalski states that "there appears to be no due diligence until January 2008."[313] January 2008 was more than 11 years ago. The fact that Cardinal does not currently possess materials reflecting due diligence conducted more than 11 years ago does not show that Cardinal conducted no due diligence of a customer before that time. As discussed elsewhere in this report, there is no DEA requirement to maintain due diligence files at all, much less a requirement to keep records dating back more than 11 years, especially when replaced with more current information. In addition, Rafalski states that New Choice stopped being a Cardinal customer in September 2015, which I understand is before this lawsuit was filed. Nonetheless, even though Cardinal was not required to maintain due diligence records relating to New Choice, the materials that I have reviewed demonstrate that Cardinal did in fact perform reasonable and appropriate due diligence on New Choice.

As with the previously discussed pharmacies, Rafalski does not provide any facts indicating that New Choice was engaged in diversion. He states that the store had high order volumes for oxycodone, but the due diligence documents show that Cardinal appropriately assured itself that New Choice was a legitimate pharmacy that was not engaged in diversion.[314] Rafalski's focus on this pharmacy based upon its order volume also ignores that Cardinal since 2012 has had in place the LV-TAC process, which subjects high volume customers to additional review, and that process resulted in this store undergoing that review as documented above.

4. Pharmed Pharmacy, Skilled Care Pharmacy, and PharMerica

Rafalski's report identifies five instances in which Cardinal shipped opioids to three pharmacies—Pharmed Pharmacy, Skilled Care Pharmacy, and PharMerica—that allegedly exceeded their respective thresholds "despite there being inadequately documented due diligence supporting the justification indicated for the release."[315] For two of these orders, Cardinal documented its justification for release as being that the orders were "not unreasonable [in] quantity, pattern, and/or frequency,"[316] which is the exact standard set by 21 CFR 1301.74(b). For the other three, the documented justification is "variation consistent with business model – no indication of diversion,"[317] which is the standard under 21 USC 823(a)(1), which the CFR seeks to implement through 21 CFR 1301.74(b). On their face, all of these entries are consistent with Cardinal personnel reviewing the orders and making the determination that they were not suspicious prior to their release. There is no indication of a lack of due diligence, the notes

[313] Rafalski Report 53.

[314] *See* Kyle Wright Deposition Tr. 165:13:166:20 (agreeing that high distribution volume does not necessarily indicate that illegal activity is occurring).

[315] Rafalski Report 64-65.

[316] *Id.*

[317] *Id.*

explaining the decisions cited by Rafalski demonstrate that due diligence was conducted, even if the underlying records are no longer available for review.[318]

In addition, Rafalski ignores other due diligence records for these customers, and neglects to mention that these three pharmacies specialize in delivering medication prescribed in acute or institutional care settings, like hospitals and long-term care facilities. Skilled Care Pharmacy is a closed door pharmacy serving long term care facilities.[319] PharMerica services skilled nursing facilities and long term care facilities.[320] Pharmed's primary customer base was long term care facilities and nursing homes, serving around 3,000 patients; it did not serve walk-in customers off the street.[321] Pharmacies that service acute or institutional care facilities have business models that are different than retail pharmacies, and variation in ordering patterns may be more readily understandable. Also, given the medical need of patients in these facilities, a shortage of medication can have significant consequences for treatment. Cardinal's decision to release these five orders was reasonable, appropriate and consistent with Cardinal's obligations under 21 CFR 1301.74(b).

I have also reviewed the data tables contained in MacDonald's Supplemental Report relating to these three pharmacies. That information shows that the pharmacies' ratios of controlled substances to non-controlled substances are quite low, [redacted].[322] In

[318] *Id.*

[319] In 2013, Cardinal Health conducted a QRA Site Visit of Skilled Care Pharmacy in which the PIC/Pharmacy Manager and Director of Pharmacy Operations participated. Cardinal Health investigator Harvey Florian viewed the dispensing data, which showed that [redacted]. He confirmed that Skilled Care "is a closed door pharmacy" and the PIC and Director "responded to questions associated with a closed door pharmacy operation that demonstrated that they understand and employ their corresponding responsibility and due diligence." CAH_MDL2804_00001699. This appears consistent with Skilled Care Pharmacy's description of its business model on its website. Skilled Care Pharmacy, *Medication Dispensing*, https://www.skilledcare.com/medication-dispensing/ ("Skilled Care Pharmacy is an institutional pharmacy that specializes in servicing long-term care facilities … including long-term care facilities for the elderly, assisted living sites, residential care, developmental disability services, schools and hospice facilities."). Cardinal Health also conducted a site visit of Skilled Care Pharmacy in May 2017. Email from Timothy Dunham Requesting Data (May 8, 2017), CAH_MDL2804_00093746; CAH_MDL2804_01624303.

[320] Due Diligence Materials, CAH_MDL2804_00001561; PharMerica, *Who We Are*, https://pharmerica.com/who-we-are/ (stating that PharMerica is redefining pharmacy services "skilled nursing facilities (SNF), long term care facilities (LTC), hospitals and other institutional care settings").

[321] CAH_MDL2804_00000150; CAH_MDL2804_00000153. Cardinal Health conducted thorough site visits of the facility that housed Pharmed's LTC pharmacy operation and its wholesaler business in October 2010 and October 2011. Wholesaler Safe Product Practices Assessment (Oct. 21, 2010), CAH_MDL2804_01001972; Wholesaler Assessment Checklist (Oct. 21, 2010), CAH_MDL2804_01001975; Wholesaler Safe Product Practices Assessment (Oct. 25, 2011), CAH_MDL2804_00000170.

[322] MacDonald Supplemental Report 8.

my opinion, those percentages are lower than the national average and do not create concerns about diversion.

5. Ross Westbank Pharmacy

Although not in Summit or Cuyahoga Counties, Rafalski devotes Schedule IV of his report to Ross Westbank Pharmacy located in Minneapolis, Minnesota.[323] Rafalski does not identify any connection between this pharmacy and Summit or Cuyahoga Counties, and in my opinion, there is not one. Based on my review of Rafalski's Schedule IV, I can see this pharmacy did not order large quantities of opioids and therefore there is no reason to suspect it is responsible for diversion into Summit or Cuyahoga Counties.

F. Opinion: Data Sources Like ARCOS and Primary Sales Records Are More Useful to DEA Diversion Investigators than Suspicious Order Reports

In my experience, DEA Diversion Investigators are trained to rely upon a variety of informational sources when investigating whether a pharmacy is diverting controlled substances. In general, investigative leads more often come from a concerned citizen or a cooperating individual than from suspicious order reports made by registrants. Additional leads could be referrals from other federal, state and local law enforcement or regulatory agencies. The ARCOS database is also a potential source of leads, particularly as that system has advanced in sophistication over time. When I began my career as a Diversion Investigator, our primary output from ARCOS consisted of quarterly reports. Evidence in this case shows that in more recent years, the ARCOS unit is capable of running customized analyses and generating leads based upon the output to their search queries. For example, Kyle Wright testified that DEA used ARCOS data to look for anomalies in the data and that, if DEA could not "resolve the anomaly, then we'd send it out to the field for investigation."[324] Tom Prevoznik similarly testified that DEA uses ARCOS data to generate leads for investigators.[325]

In my experience, suspicious order reporting plays a lesser role in generating investigative leads as compared citizens' complaints, cooperating witness information, or referrals from other agencies. In my opinion, a trained Diversion Investigator would not act solely on a suspicious order report, but instead would expound or attempt to verify the information by requesting sales information from the distributor and other distributors in the area or conduct an inspection of the pharmacy's primary records, such as Form 222's, controlled substances invoices, and controlled substance prescriptions.

It is also my opinion, that the inadvertent failure to report four orders for pharmacies located in Cuyahoga and Summit Counties (discussed above) cannot reasonably be expected to have impacted the work of DEA Diversion Investigators. As noted above, those orders were not shipped and therefore did not enter the marketplace. Suspicious order reports generally have a

[323] Rafalski Report 61 n.208 and Schedule IV.

[324] Kyle Wright Deposition Tr. 172:10-173:17.

[325] Tom Prevoznik Deposition Tr. 337:2-338:15, 498:4

limited investigative value on their own, and typically do not lead to the opening of investigations on their own. Such reports would most likely have been consulted only to the extent that there was additional information supporting the initiation of an investigation into those pharmacies, and in that event, there are other available law enforcement tools that would have allowed a trained Diversion Investigator to obtain information necessary to evaluate the pharmacies' conduct.

G. Opinion: Plaintiffs' Proposed Suspicious Order Criteria Are Unreasonable, Not Required, and Would Not Have Met DEA's Expectations

I have reviewed Plaintiffs' proposed alternative methodologies for identifying suspicious orders as described in the report of McCann and to a lesser extent, Rafalski.[326] In my opinion, these alternative methodologies are not appropriate for identifying suspicious orders for several reasons. Just as important, even if these methodologies were appropriate, that would at most make them an option that a registrant could have followed to identify suspicious orders, not ones that they had to follow. Nothing in the CFR or DEA's policies supports the proposition that the failure to use one of the Plaintiffs' specific methodologies means that a registrant has acted unreasonably or that it has failed to maintain a valid system for detecting and reporting suspicious orders. In my opinion, the methodologies actually used by Cardinal (discussed previously) are superior to those identified by Plaintiffs' witnesses in several ways.

To understand the flaws in Plaintiffs' methodologies, it helps to understand the proper expectations of an SOM program in the context of two goals held simultaneously by DEA: preventing diversion and ensuring patients' access to legitimately prescribed medications. According to statistics published by the DEA, more than half of all misuse of prescription opioid medication involves medication that was diverted after it was issued to the ultimate user (i.e., the patient to whom it was prescribed). Opioids diverted in that manner have already left the closed system of distribution, and are diverted when they are taken from homes, sold or given to friends or relatives, or similar scenarios.[327] Because medication diverted in that manner was dispensed to patients before being diverted, it is by definition no longer the responsibility of (or even under the control of) DEA registrants. A well-designed SOM program cannot possibly be expected to identify or prevent that type of diversion even though it constitutes the majority of all diversion. Instead, the realistic goal of any SOM program is to detect orders that may contribute to the lesser share of diversion that occurs within the closed system of distribution.

DEA also seeks to discharge its responsibilities under the CSA in a manner that does not interrupt access to prescription pharmaceuticals for patients with legitimate medical needs. Prescription opioids are FDA approved medications that may be prescribed and dispensed

[326] McCann Report 56-76; Rafalski Report 40-46.

[327] DEA 2018 National Drug Threat Assessment at 7-8 (showing 53.1% of persons reporting misusing prescription opioids were "given by, bought from, or took from a friend or relative."). Additional percentages reflect amounts purchased from drug dealers (6%), or stolen from health care providers (0.7%). Id.

consistent with applicable standards of medical care.[328] At various times, DEA has published statements reflecting these twin responsibilities. For example, on September 6, 2006, DEA published in the Federal Register a notice titled, "Dispensing Controlled Substances for the Treatment of Pain."[329] In the notice, DEA discussed the extent of the drug abuse of controlled substances in the U.S. DEA cited the following information:

> One of the areas of concern is the number of persons who have recently begun abusing prescription controlled substances. In its NSDUH Report published in June 2006, SAMHSA states: "In 2004, among persons aged 12 or older, 2.4 million initiated nonmedical use of prescription pain relievers within the past year. This is more than the estimated number of initiates for marijuana (2.1 million) or cocaine (1.0 million)." Overall, according to the NSDUH report: "An estimated 31.8 million Americans have used pain relievers nonmedically in their lifetimes, up from 29.6 million in 2002."
>
> Another source of data presented by SAMHSA is that collected by the Drug Abuse Warning Network (DAWN), which provides national estimates of drug related visits to hospital emergency departments. According to DAWN, for 2004:
>
> - Nearly 1.3 million emergency department (ED) visits in 2004 were associated with drug misuse/abuse. Nonmedical use of pharmaceuticals was involved in nearly half a million of these ED visits.
>
> - Opiates/opioid analgesics (pain killers), such as hydrocodone, oxycodone, and methadone, and benzodiazepines, such as alprazolam and clonazepam, were present in more than 100,000 ED visits associated with nonmedical use of pharmaceuticals in 2004.
>
> A measure of the problem among young people is the 2005 Monitoring the Future (MTF) survey conducted by the University of Michigan. The MTF survey is funded by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), and measures drug abuse among 8th, 10th, and 12th graders. NIDA stated: "While the 2005 survey showed a continuing general decline in drug use, there are continued high rates of non-medical use of prescription medications, especially opioid pain killers. For example, in 2005, 9.5 percent of 12th graders reported using Vicodin in the past year, and 5.5 percent of these students reported using OxyContin in the past year." In announcing the latest

[328] It is beyond the scope of my assignment, and my expertise, to comment upon the range of therapeutic uses for prescription opioids that are consistent with applicable medical standards. The point is simply that these medications have legitimate medical uses, and DEA seeks not to interfere with those legitimate medical uses.

[329] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006).

> MTF survey results, NIH Director Dr. Elias Zerhouni said that "the upward trend in prescription drug abuse is disturbing."[330]

Despite registering DEA's concern for prescription opioid abuse, the same statement went on to say: "DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials. Contrary to the impression of some commenters, DEA has not modified its criteria for investigating physicians or increased its emphasis on physicians as part of the agency's overall mission. In any given year, including 2005, fewer than one out of every 10,000 physicians in the United States (less than 0.01 percent) lose their controlled substance registrations based on a DEA investigation of improper prescribing. This figure alone should correct any mistaken notions about a supposed DEA 'crackdown' on physicians. Moreover, as mentioned above, the responsibility for monitoring and preventing controlled substance abuse is shared by State and Federal governments. Even in the rare cases where a physician loses his/her DEA registration for improper prescribing, it is often State officials--not DEA--who initiate the investigations."[331]

DEA also made the following statement in the November 16, 2004, Interim Policy Statement published in the Federal Register: "[C]hronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified."[332] In the 2006 notice, DEA states, "it is not DEA's role to issue medical guidelines specifying patient characteristics that warrant the selection of a particular opioid or other medication or regimen for the treatment of pain."[333]

Joe Rannazzisi similarly testified before Congress that "99.5 percent of the prescribers … are not overprescribing."[334]

Rannazzisi has also testified that although DEA has the ability to reduce the overall supply of prescription opioids through its control of production quotas, it would not be appropriate for DEA to exercise that authority to try and force a shortage of medication so as to prevent downstream diversion and misuse:

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[330] *Id.*

[331] *Id.* at 52,720.

[332] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 (Nov. 16, 2004).

[333] 71 Fed. Reg. 52,716, at 52,718.

[334] Joe Rannazzisi Deposition Tr. 191:4-193:9; *see also* "Prescription Drug Diversion: Combating the Scourge," Hearing before the Subcommittee on Commerce, Manufacturing, and Trade (Mar. 1, 2012), at 94 (Rannazzisi testifying that "99 percent of the doctors are perfect").

> Quota is not a tool to stop diversion. Quota is a tool to limit the amount of drug available, you know, from a manufacturer, a distributor, but in the end, the reason Congress set it up that way and the reason it was explained to me was that if there is not enough quota to meet the legitimate medical, scientific and industrial needs of the country, legitimate patients could not -- would not be able to get their medicine.
>
> That is, if we have a quota and we decide to cut the quota by 20 percent, you still have the same amount of people kind of drawing from that quota. Well, if it's 20 percent less, patients might not get their medication. If it's a drug seeker, you know, no one really cares, but if it's a – if it's a person who actually needs that opioid, a hospice care patient, a palliative care patient, somebody that indeed needs opioids for transition or whatever, you know, their final stages of life. If they can't get that medication, they are in pain, then we haven't met our obligations under 826.[335]

Consistent with these twin concerns, it is not a legitimate goal of a well-designed SOM program to have distributors seek to change medical standards or deprive patients of prescribed medications by creating artificial shortages. In addition to being outside the legitimate goals of the DEA as a regulator, such an approach would be inconsistent with the regulatory definition of a "suspicious order" as being an order of unusual size, frequency, or pattern. By definition, a level of ordering that is consistent with prevailing medical standards is not "unusual" by these criteria, and an SOM program cannot be expected to treat the vast majority of orders as suspicious consistent with the definition in the CFR.

In my opinion, Plaintiffs' proposed methods for identifying suspicious orders are incompatible with the regulatory definition of suspicious orders, and reflect the misguided aim of making distributors responsible for second-guessing legitimate medical need. As noted in Rafalski, these methods would label between 40.4% and 96.6% of the dosage units ordered by Cardinal's customers as "suspicious."[336] These criteria are not reasonable. The purpose of the Suspicious Order Reporting regulation is to require registrants to review "unusual" orders, not ordinary orders. Methodologies that reflexively result in that high of a share of all orders being identified as "unusual" would appear not to satisfy the regulation. In addition, these methods would dilute the value of the information reported to DEA, making it harder to identify those orders that a registrant truly regards as suspicious based on its knowledge of its customers.

Plaintiffs' suggestion that there are a limited set of thresholds that a distributor can reasonably use is misguided. DEA has expressly and repeatedly explained that there is no particular set of criteria that must be used to flag potentially suspicious orders. For example, Rannazzisi testified

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[335] Joe Rannazzisi Deposition Tr. 499:16-500:14.

[336] Rafalski Report 41-46. Under the "Maximum Monthly, Trailing 6 Month Threshold" methodology that Rafalski endorses, 96.6% of oxycodone and 93.6% of hydrocodone dosage units that Cardinal distributed in Cuyahoga County would be part of suspicious orders. *Id.* In Summit County, 92.7% of oxycodone and 90.4% of hydrocodone dosage units that Cardinal Health distributed would be part of suspicious orders. *Id.*

that compliance with 1301.74(b) involves "a business decision based on what the registrant's needs are and the Drug Enforcement Administration does not tell a registrant what that specific system should look like."[337] Wright testified that DEA understood that "not every company would necessarily have the exact same type of program" and that "DEA wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might service."[338] Prevoznik testified that "there's more than one way to design and operate a system that can identify and report suspicious orders" and that "there's no single feature that makes a suspicious order monitoring system compliant."[339] If Cardinal had reported more than 80% of its orders as suspicious, it is highly probable DEA would have instructed it to stop doing so. Further, DEA requires registrants to incorporate knowledge of their customers into any assessment of what constitutes a "suspicious" order, and Plaintiffs' proposed methods are deliberately blind to variations in customer circumstances that may justify different order sizes, frequency or patterns for differently situated customers. In contrast, the methods actually adopted by Cardinal (which I have reviewed above), appropriately account for Cardinal's knowledge of its customers, and therefore are more compatible with the CFR and DEA policy than the ones proposed by Plaintiffs.

[337] Joe Rannazzisi Deposition Tr. 315:17:316:12.

[338] Kyle Wright Deposition Tr. 128:14-129:1

[339] Tom Prevoznik Deposition Tr. 179:22-180:11.

Materials Considered

I. Pleadings

Cuyahoga County's Second Amended Corrected Complaint dated May 25, 2018

II. Defendants' Expert Reports

Expert report of John J. MacDonald dated May 10, 2019

Supplemental Expert Report of John J. MacDonald dated May 31, 2019

Expert report of Catherine Rahilly-Tierney M.D., M.P.H Expert Witness Report dated May 10, 2019

III. Plaintiffs' Expert Reports

Expert Report of Craig J. McCann dated March 25, 2019 including Appendices

Expert Report of James E. Rafalski dated April 15, 2019 including Schedule IV

Expert Report of Dr. Stephen W. Schondelmeyer dated April 14, 2019

Expert Report of Dr. Seth Whitelaw dated April 15, 2019 including Appendices and citations

IV. Depositions

a. Defendant Depositions

Deposition of Eric Brantley dated November 27, 2018
Deposition of Todd Cameron dated September 26, 2018
Deposition of Raymond P. Carney dated October 16, 2018
Deposition of Douglas Emma dated January 17, 2019
Deposition of Christopher J. Forst dated January 22, 2019
Deposition of Mark Hartman dated November 15, 2018
Deposition of Kim Howenstein dated January 10, 2019
Deposition of Shirlene Justus dated July 13, 2018
Deposition of Donald Steven Morse dated December 13, 2018
Deposition of Jennifer Norris dated August 7, 2018
Deposition of Nicholas Rausch dated November 11, 2018
Deposition of Steve Reardon dated November 30, 2018 including exhibits 39, 40, 41
Deposition of Gilberto Quintero dated December 6, 2018
Deposition of Kimberly S. Anna-Soisson dated January 24, 2019

b. DEA Depositions

Deposition of June Howard dated April 25, 2019
Deposition of Thomas Prevoznik dated April 17, 2019
Deposition of Thomas Prevoznik dated April 18, 2019
Deposition of Thomas Prevoznik dated May 17, 2019
Deposition of Joseph Rannazzisi dated April 26, 2019
Deposition of Joseph Rannazzisi dated May 15, 2019
Deposition of Kyle Wright dated February 28, 2019
Deposition of Kyle Wright dated March 4, 2019

V. Publicly Available Documents

Congressional Testimony of Joseph Rannazzisi dated March 1, 2012 (https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/03/01/12/03-01-12-dea-rannazzisi-testimony.pdf)

Congressional Testimony of Michele Leonhart dated September 18, 2014 (https://www.hsdl.org/?abstract&did=758373)

Controlled Substances and List I Chemical Registration and Reregistration Fees, 76 Fed. Reg. 39,318 dated July 6, 2011

DEA Policy Statement - Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 dated September 6, 2006

DEA Press Release - Operation Synthetic Opioid Surge dated July 12, 2018 (https://www.dea.gov/press-releases/2018/07/12/operation-synthetic-opioid-surge-new-program-announced-attorney-general)

DEA Testimony of Paul E. Knierim on Trafficking of Illegal Fentanyl from China dated October 2, 2018 (https://www.dea.gov/sites/default/files/2018-10/DEA%20Testimony%20-International%20Drugs%20-%20Senate%20Drug%20Caucus_2Oct18_final.pdf)

Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170 dated November 16, 2004 (https://www.govinfo.gov/content/pkg/FR-2004-11-16/pdf/04-25469.pdf)

Drug Enforcement Administration, Controlled Substances and Pain Management Article dated September 2001 (https://web.archive.org/web/20011205021713/http://www.deadiversion.usdoj.gov/pubs/nwslttr/spec2001/page10.htm)

Full Year 2008 Performance Budget – Congressional Budget Submission (https://www.justice.gov/archive/jmd/2008justification/pdf/35_dea.pdf)

Full Year 2011 Performance Budget – Congressional Budget Submission (https://www.justice.gov/sites/default/files/jmd/legacy/2014/05/29/fy11-dea-justification.pdf)

GAO Report – More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access dated June 2015 (https://www.gao.gov/assets/680/671032.pdf)

GAO Report – DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results dated August 2011 (https://www.gao.gov/assets/520/511464.pdf)

Joint Statement from 21 Health Organizations and the Drug Enforcement Administration dated 2001 (https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf)

Joseph Rannazzisi answers to House Committee's questions dated May 1, 2015 (https://www.dea.gov/sites/default/files/pr/speeches-testimony/2014t/04072014t.pdf)

Minutes of the July 7-8, 2008 Meeting of the Ohio State Board of Pharmacy (https://www.pharmacy.ohio.gov/Documents/Pubs/Minutes/2008/200807%20-%20Minutes%20(Jul%202008).pdf)

News Release – Drug Enforcement Administration, 21 Health Groups Call for Balanced Policy on Prescription Pain Medications like OxyContin dated October 23, 2001 (https://www.deadiversion.usdoj.gov/pubs/advisories/newsrel_102301.pdf)

2018 National Drug Threat Assessment (https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20final%20low%20resolution.pdf)

State of Ohio Board of Pharmacy Rules Update – Drug Distributors – Spring 2019 (https://www.pharmacy.ohio.gov/Documents/LawsRules/RuleChanges/Year/2019/Rules%20Update%20-%20Drug%20Distributors%20-%20Spring%202019.pdf)

VI. Statutes and Regulations

21 U.S. Code Chapter 13 (Controlled Substances Act)
21 CFR Parts 1300-1308, 1316

VII. Production Documents

ABDCMDL00315783
CAH_MDL_PRIORPROD_AG_0001241
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US-DEA-00025683

VIII. Discovery Responses

Cardinal Health's written responses to certain topics identified in Plaintiffs' First and Second Notice of Deposition Pursuant to Rule 30(b)(6) dated October 18, 2018

Cardinal Health's written responses to certain topics identified in Plaintiffs' Second Notice of Deposition Pursuant to Rule 30(b)(6) dated November 14, 2018

Cardinal Health's Supplemental Response to 30(b)(6) Testimony Topic (a) dated January 24, 2019

Cardinal Health's Third Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests dated March 4, 2019

Cardinal Health's written Revised and Supplemental Response to 30(b)(6) Testimony Topic (a) dated March 4, 2019

Cardinal Health's Second Supplemental Response to 30(b)(6) Testimony Topic 16 Topic (a) dated March 4, 2019